

1.5.2 Butyrophenones

HALOPERIDOL OETHMAAN, Oethmaan Biosims [P/S]

Haloperidol.

Indications: Ac. & chron. schizophren., mania, ac. psychos.

(S5) TABS, Q/2.6.5/169, 170

730335-003: 1.5 mg, 60, [R89,61](#)

730327-028: 5 mg, 100, [R118,77](#)

Dosage: Indiv. Adults: 6-12 mg/day which may be incr. to 45 mg/day. High dos.therapy of 200 mg dly has been used. Maint.dos: 1,5-3 mg/day. Childr. over 3 yrs:

Maint.dos: 0,05 mg/kg bw/day in 2 div.dos. Reduc.dos. to half of adult dos. in elderly/ debilitat.pts.

Contraindications: Monother.where depress. predomin., CNS depress., comatose states, bone marr.suppress., phaeochromocyt., leucopen. induc.meds.incl.

phenylbutazone & thiouracil derivs., childr.und.3 yrs., safety in pregn.& lactat. not est.

Side effects: Freq: Akathis., ac.dystonic reacts., Parkinson.syndr., dry mouth, constip., blurr.vis., mydrias., tachycard., ECG chang., card.arrhythm.; amenorrh, galactorrh, breast.swell./soreness, unusual secret.of milk., weight gain. Less freq: Tard. dyskines., neurolept.malign.syndr., perior. trem., "rabbit" syndr., diffic.micturit., hypotens.; delir., agitat., cataton.-like states, insomn., drowsin., dizzin., sweat., convuls., depress., imp. body temp.regulat., hypo-/ hypertherm., EEG changes; ejaculat.inhibit, impot., priapism, gynaecomast., decr.thirst, weight loss, SLE-like syndr., deposit.of pigment in skin, photosens. reacts., nas.congest., deposit.of pigment in eyes; corneal/lens opacities, hyperglycaem., alt.gluc. tol., jaund., haemolyt.anaem., aplast.anaem., thrombocytopen. purpura., potent.fatal agranulocytos., leucopen., oed., GI disturbs., naus., vomit., urin.retent., hypersens.react.

Warnings and special precautions: Consid.risk profile in pts.with epilep./Parkinson's/urin.retent. bef.start.treatm., childr.suscept.to extrapyramid. S/E incl.dyston., elderly, epilept.receiv.anticonvuls. as seiz. thresh.poss.low., imp.liv.funct., hist.of jaund., imp.kidn./CV/cerebrovasc./resp.funct., clos. angle glauc., parkinson, diab.mellit., hypothyroid., myasth.grav., prostat.hyperplas, dos. adjustm.with other agents that produc.postur.hypotens., periodic. exam.for abnorm.skin pigmentat./ eye changes, may mask sympts of OD/GI obstruct. because of eff.on vomit.centre, body temp.regulat. imp., avoid.direct sunlight, bld.counts advis.if pt develops unexplain.infects., developm.of dent. caries/ periodont.dis./oral candidias.due to poss. decr./inhib.saliv.flow & microb. infect/del.heal./ gingiv.bleed.due to leucopen. & thrombocytopen. eff., defer.dent.work if leucopen./thrombocytopen. occ.until bld.counts return to norm., proper pt.oral hygiene., lact.intol., concom.anticoaqs.

Drug interactions: CNS depress.act.potent., alcoh. may low.tresh.of resist.to neurotox.effs., anti-arrhythm.which prolong QT interv.incr. likelihood of ventr.arrhythm., antihypertens.act.of guanethidine & other adrenerg.neur.blocks.reduc., may potent.adverse eff.of other anticholinerg., incr. CNS adverse eff.with fluoxetine., dos.of oral hypoglycaem.meds may need adjust., carbamazepine decr.ser.lev., incr.clear.with rifampicin, incr.risk of neurolog.tox.with concom. Li., reduc.plasma conc. with Al/Mg contain. antacids., metoclopramide incr.risk of neurolept.-induc. extrapyramid.eff, incr.ser.prolactin conc. with bromocriptine, incr.seiz.risk with bupropion, eff.of levodopa/pergolide decr., pressor respon.to metaraminol decr., periph.vasoconstrict.eff.of dopamine poss.reduc., adverse ment.eff.incr.with methyl dopa.

1.5.3 Atypical antipsychotics

ABILIFY, Lundbeck [P/S]

Aripiprazole

Indications: Schizophren. & maint.of clinic. improvem. in adults, ac.manic episod.assoc.with Bipol.1 disord., prevent.of recurr.new manic episod. in

pts.exper.predomin.manic episod.& who respond.to Abilify ther.

(S5) TABS, 41/2.6.5/0493, A38/2.6.5/0595, 0596

712192-001: 5 mg, 30, [R918,99](#)

705634-001: 10 mg, 30, [R1 298,68](#)

705635-001: 15 mg, 30, [R1 603,67](#)

Dosage: Schizophren: Recomm.start.dos.10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Dos.range: 10-30 mg/day. Enhanc.effic.at dos. high. than recomm.15

mg/day not demonstrat. Indiv. may benef.from high.dos. Max.dly.dos.not to exceed 30 mg/day.

Bipol.mania: Recomm.start.dos.15 mg once dly. as monother./combin.ther. Indiv.may benef.from high.dos. Max.dly.dos.not to exceed 30 mg.

Prevent.of recurr. manic episod.in pts. receiv. Abilify: Cont.ther.at same dos. Dly.dos. adjustm. incl.dos.reduct.to be consid.on clinic.status. Depress. episod.prevent.with monother.has not been est. Consid.clinic.approp.supplem.ther.for prevent./treatm.of depress.episod.

Concom.meds: With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual Abilify dos. Incr.dos. when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc:

Double Abilify dos. Addit.dos.incr.based on clinic.eval. Abilify dos.to be reduc.when concom.CYP3A4 induc.is withdr.

(S5) MAINTENA SUSP.FOR INJ, 48/2.6.5/0531

3002581-001: 400 mg, 1x2 ml pre-filled syringe, [R6220,21](#)

3002583-001: 400 mg, 1x2 ml vial kit, [R6220,21](#)

Indications: Maint.treatm.of schizophren.in adults stabilis.with oral aripiprazole

Dosage: Admin. as IM inject.into gluteal/deltoid musc. Keep prolong.release characterist.in mind when discont.treatm.

Recomm.start.& maint.dos: 400 mg admin. 1x/ mnth. as a sngl.inj.(> 26 days aft. prev.inj.). Contin. treatm.with 10-20 mg oral aripiprazole per day for 14 consecut.days

aft.the 1st inj.to maint.therapeut. conc. dur.initiat.of ther. Dos.may be reduc.to 300 mg in case of adv.reacts. Ref.to product lit.for dos.adj.in case of missed dos.

Concom.meds: Dos.adjust.advis.with concom. strong CYP2D6/ CYP3A4 inhibits.&/CYP3A4 induc. taken for more than 14 days. Ref.to product lit.for recomm.dos.adj.

Contraindications: Safety& effic.in pts.und.18 yrs./ pregn.& lactat.not est., dement.-relat. psychos., Maintena inj.: IV/SC inj.

Side effects: V.common: Insomn., naus. Common: Asthen./fatig., blurr.vis., constip., vomit., saliv. hypersecret., dyspeps., stomach discomf., dizzin., akathis., somnol./sedat., trem,fatig., musculoskelet. stiffn., dyspeps., orthostat. hypotens., restlessn., anx., extrapyramid.disord., tachycard., hyperprolactinaem., erectile dysfunct.

Maintena inj.: Inj.site pain/indurat. Uncommon: Periph. oed, headache., gait disturb., chest discomf., glycosur., galactorrh., gynaecomast., breast tendern.,

vulvovagin. dryn., musc.rigidity/spasms/twitch/tightn., pain in extremity., arthralg., back pain, joint range of mot.decr., n uchal rigid., trismus., acne, rosac., eczema, skin

indurat., incr. hepat.enz., cough, hiccups., GORD, oculogyr.crisis, eye pain, Parkinson., movem.disord., psychomot.hyperactiv., restl.legs syndr., cogwheel rigid., hyperton.,

bradykines., drool., dysgeus., parosmia, decr.WBC, psych.disords., ECG abnormalit. Maintena inj.: Inj.site reacts./erythem./swell./discomf./prurit. Unknown: NMS, seiz.,

tard.dyskines., leucopen., neutropen., thrombocytopen., agitat., impulse contr. disords., suic. ttempt/ideat./complet., poriomani., aggress., nervousn., speech disord., grand

mal convuls., serotonin.syndr., diplop., sudd. unexplain.death, Torsades de pointes, QT prolongat., ventric.dysrhythm., card.arrest., bradycard., syncope, hypertens., ven.

thromboembol., pancreat., dysphag., diarrh., temp. regulat.disord., chest pain, periph.oed., allerg. react., hyperhidros., alopec., photosens., rhabdomyolys., myalg.,

musculoskelet. stiffn., priap., urin.retent./incontin, aspirat.pneumon., hiccups, oropharyng.spasm, hepat.fail., hepatit., jaund., hyponatraem., anorex., incr./decr.weight

Warnings and special precautions: Monit.pt. clos. as clinic.improvem.may take sev.days to wks., monit. high risk pts.for suic., overdos.risk, reconsid. dos. reduct./discont.if

sympts.of tard.dyskines. devel., discont.all antipsychot.meds.if S&S of neurolept. malign.syndr.develop/unexpl.high fev. without addit.clin.manifestats.of NMS, seiz.disord.

hist./ assoc.condit., incr.fatalit.(prim.CV/infect.) report. in elderly with dement.-relat.psychos., safety of Maintena inj.not est.in pts.> 65 yrs./ sev. hepat.impairm.,

monit.diab.mellit./high risk pts.for worsen.control & do fast.bld.gluc.for pts.develop. hyperglycaem. sympts., hyperglycaem.may resolv. on discont.but instanc.may

req.contr.anti-diab.ther., concom.CNS act.drugs/stimul, avoid concom. alcoh., consid.benef.vs.risk with concom. ketoconazole/ other potent. CYP3A4 inhibits.

incl.itraconazole/HIV protease inhibits., known CV/cerebrovasc.dis., concom.meds.known to prolong QT interv./family hist.of QT prolongat., condits. predispos.to

hypotens.(incl.hypovolaem./treatm. with antihypertens.) or hypertens., identify VTE risk facts.bef./dur.ther.& prevent.meas.taken., elev. core body

temp.condits.incl.concom. anticholinergs./dehydrat., oesophag.dysmotil.& aspirat. assoc.with antipsychot.drug use theref. care in aspirat.pneum.risk pts., monit.for

developm. of new/incr.gambling urges/sexual urges/ compuls.spend./binge or compuls.eat./other urges. & consid dos.reduct./discont.treatm if pt. dev.such urges,

lact.intol., pts.at risk of fall.& consid. low.start.dos. Maintena inj: not for managem. of ac.agitat./sev.psychot.states when immed. sympt.contr.warrant.

Interactions: Cert.antihypertens.effs.poss. enhanc., AUC incr.by quinidine & other potent CYP2D6 inhibits.incl.fluoxetine/paroxetine/ quinidine, AUC & C_{max} incr.by

ketoconazole/other potent CYP3A4 inhibits, decr.AUC & C_{max} with valproate/ carbamazepine/other potent CYP3A4 induc., risk of serotonin.syndr.with concom.SSRI/

SNRI/meds. known to incr.aripiprazole conc., modest incr.in plasma conc.with weak inhibits.of CYP3A4 (e.g. diltiazem)/CYP2D6 (e.g. escitalopram)

ABIPIP, Cipla Medpro [P/S]

Aripiprazole

Indications: Schizophren. & maint.of clinic. improvem. in adults, ac.manic episod.assoc.with Bipol.1 disord., prevent.of recurr.new manic episod. in

pts.exper.predomin.manic episod.& who respond.to Abipip ther.

(S5) TABS, 51/2.6.5/0667.663, 0668.664, 0669.665

3001454-001: 5 mg, 30, [R233,10](#)

3001455-001: 10 mg, 30, [R390,00](#)

3001456-001: 15 mg, 30, [R660,00](#)

Dosage: Recomm.start.dos.10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Dos.range: 10-30 mg/day. Enhanc.effic.at dos.high.than recomm. 15 mg/day not demonstrat. Indiv may benef.from high.dos. Max.dly.dos.not to exceed 30 mg/day.

Bipol.mania: Recomm.start.dos.15 mg once dly. as monother./combin.ther. Indiv.may benef.from high.dos. Max.dly.dos.not to exceed 30 mg.

Prevent.of recurr. manic episod.in pts.receive. Abipip: Cont.ther.at same dos. Dly.dos. adjustm. incl.dos.reduct.to be consid.on clinic.status. Depress. episod.prevent.with monother.has not been est. Consid.clinic.approp.supplem.ther.for prevent./treatm.of depress.episod.

Concom.meds: With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual dos. Incr.dos.when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc: Double dos. Addit.dos. incr. based on clinic.eval. Dos.to be reduc.when concom. CYP3A4 induc.is withdr.

(\$5) ODT ORODISPERS.TABS, 51/2.6.5/0674.671, 0675.672

3003284-001: 10 mg, 28, **R364,00**

3003286-001: 15 mg, 28, **R616,00**

Dosage: Place tab.on tongue to disperse./ dissolve in water & drink result.supsens.

Recomm.start.dos: 10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Dos.range: 10-30 mg/day. Enhanc.effic.at dos.high.than recomm. 15 mg/day not demonstrat. Indiv may benef.from high.dos. Max.dly.dos.not to exceed 30 mg/day.

Bipol.mania: Recomm.start.dos: 15 mg once dly. as monother./combin.ther. Indiv.may benef. from high.dos. Max.dly.dos.not to exceed 30 mg.

Prevent.of recurr. manic episod.in pts.receive. Abipip: Cont.ther.at same dos. Dly.dos. adjustm. incl.dos.reduct.to be consid.on clinic.status. Depress. episod.prevent.with monother.has not been est. Consid.clinic.approp.supplem.ther.for prevent./treatm.of depress.episod.

Concom.meds: With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual dos. Incr.dos.when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc: Double dos. Addit.dos. incr. based on clinic.eval. Dos.to be reduc.when concom. CYP3A4 induc.is withdr.

Contraindications: Elderly pts.with *dement.-relat. psychos, safety & effic. in pts.und.18 yrs./ pregn.& lactat.not est.*

Side effects: Freq: Weight gain, diabet.mellit., insomn., somnol., sedat., restless., anx., agit., headache, dizzin., lightheadedn., akathis., trem., extrapyramid.disord., blurr.vis., N&V, dyspeps., constip., saliv.hypersecret., asthen./fatig. Less freq: Tard.dyskines., dyston., hyperprolactinem., depress., hypersex., diplop., tachycard., orthostat.hypotens., hiccups. Freq.unknown: Agranulocytos., leukopen., neutropen., thrombocytopen., allerg.react., anaphylact.react., angioed., diabet.ketoacidosis., diabet.hyperosmol.coma, weight decr., anorex., hyponatraem., hyperglycaem., nervousn., pathologic.gambling, suic. attempt/ ideat., speech disord., NMS, grand mal convuls., seroton.syndr., seiz., suicide complet., QT prolongat., ventric.dysrhythm., sudd. unexplain.death, card.arrest, torsade de pointes, bradycard., syncope, hypertens., ven. thromboembol., cerebrovasc.accid, oropharyng. spasm, laryngospasm, aspirat. pneumon., cough, pancreatit., dysphag., dry mouth, abdom./stomach discomf., diarrh., jaund., hepatit., hepat.fail., incr. ALT/AST/GGT/alkaline phosphat., rash, photosens.react., alopec., hyperhidros., rhabdomyolys., myalg., stiffn., urin.incontin./retent., neonat.med. withdraw.syndr, priapism, temp.regulat.disord, chest pain, periph.oed., incr.creatine phosphokinase/ bld.gluc., bld gluc.fluctuat., incr. glycosylat.haemoglob.

Warnings and special precautions: *Incr. fatalit. (prim.CV/infect.) report.in elderly with dement.-relat.psychos., monit.pt.clos.as clinic. improvem.may take sev.days to wks., monit.high risk pts.for suic., overdos.risk, recondid.dos. reduct./discont.if sympt.of tard.dyskines.devel., monit. pts.with prior hist.of pathologic.gambling, discont. all antipsychot.meds.if S&S of neurolept. malign. syndr.develop/unexpl.high fev.without addit. clin.manifestats.of NMS, seiz.disord.hist./ assoc.condit., dement.-relat. psychos./behav. disturbs., elderly pts., falls & fract.risk, monit.diab. mellit./high risk pts.for worsen.control & do fast.bld.gluc.for pts. develop.hyperglycaem. sympts., hyperglycaem.may resolv.on discont.but instanc.may req.cont. anti-diab.ther., concom.CNS act.drugs, avoid concom.alcoh., consid.benef. vs.risk with concom.ketoconazole/other potent. CYP3A4 inhibits.incl.itraconazole/HIV protease inhibits., known CV/ cerebrovasc.dis., concom. meds.known to prolong QT interv., famil.hist.of QT prolongat., condits.predispos.to hypotens.incl. hypovolaem./treatm.with antihypertens., poss. orthostat.hypotens.due to α 1-adrenerg.recept. antagon., hypertens.incl.accelerat./malign., potent. for cognit. & motor impairm., identify all poss.risk facts.for VTE bef. & dur.treatm.& undertake preventat.meas.as reqd., reduc.dos.in cas.of clin. signif. weight gain., elev.core body temp.condits. incl. concom.anticholinergs./dehydrat., oesophag. dysmotil.& aspirat.assoc.with antipsychot.drug use theref. care in aspirat.pneum.risk pts., monit.CBC in pts. with hist.of clin.signif.low WBC/med.-induc. leukopen./neutropen.dur.first few mnths of ther., discont. at first sign of clin.signif.decline in WBC in absence.of other causat.facts., lact.intol., concom. stimul in ADHD pts., effic. in long-term use not est., monit.pts.on parenter.benzodiazep. ther. for excess.sedat./orthostat.hypotens.*

Interactions: *Cert.anti hypertens.effs.poss. enhanc., AUC incr.by quinidine & other potent CYP2D6 inhibits.incl.fluoxetine/paroxetine, AUC & C_{max}.incr.by ketoconazole/other potent CYP3A4 inhibits, decr.AUC & C_{max} with valproate/ carbamazepine/ other potent CYP3A4 induc., mod. incr. conc.with concom.diltiazem/escitalopram, reduc.rate of absorpt.with concom.famotidine, concom. serotonerg. meds.such as SSRIs/SNRIs may inr risk or seroton.syndr.*

ALEBON, Aurogen [P/5]

Aripiprazole

Indications: Schizophren. & maint.of clinic. improvem. in adults, ac.manic episod.assoc.with bipolar.1 disord., prevent.of recurr.new manic episod. in pts.exper.predomin.manic episod.& who respond.to treatm.

(\$5) TABS, 47/2.6.5/1080, 1081, 1082

3005146-001: 5 mg, 30, **R230,00**

3005147-001: 10 mg, 30, **R385,00**

3005148-001: 15 mg, 30, **R662,00**

Dosage: Schizophren: Recomm.start.dos.10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Effect.dos. range: 10-30 mg/day. Enhanc.effic.at dos.high. than recomm. 15 mg/day not demonstrat. Indiv.pt. may benef. from high.dos. Max.dly.dos.not to exceed 30 mg/day.

Bipol.mania: Recomm.start.dos 15 mg once dly. as mono-/combin.ther. Indiv.pt.may benef.from high.dose. Max.dly.dos.not to exceed 30 mg.

Prevent.of recurr.manic episod.in bipolar I: Cont. ther.at same dos. Consid.dly.dos.adjustm. incl.dos.reduct.on clinic.status. Depress. episod. prevent. with monother. not est. Consid. clinic. appropr.supplem.ther.for prevent./treatm.of depress.episod.

Concom.meds: With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual dos. Incr.dos.when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc: Double dos. Addit.dos. incr. bas.on clinic.eval. Dos.to be reduc.when concom. CYP3A4 induc. withdr.

Contraindications: *Safety & effic. in pts.und.18 yrs.not est.*

Side effects: Freq: Diabet.mellit., insomn., restless., anx., headache, dizzin., akathis., somnol., sedat., trem., extrapyramid. disord., blurr.vis., N&V, dyspeps., constip., saliv.hypersecret., fatig. Less freq: Hyperprolactinem., hyperglycaem., depress., hypersex., tard.dyskines., dyston., diplop., tachycard., orthostat.hypotens., hiccups. Freq.unknown: Leucopen., neutropen., thrombocytopen., allerg.react., anaphylact.react., angioed., diabet.ketoacidosis., diabet.hyperosmol.coma, anorex., hyponatraem., weight gain/dec., suic.attempt/ideat./-complet., pathologic.gambling, impuls.contr.disords.binge eat., compuls.shop., poriomani., aggress., agit., nervousn., NMS, grand mal convuls., seroton.syndr., speech disord., oculogyri.crisis, QT prolongat., ventric.dysrhythm., card.arrest, torsade de pointes, bradycard., sudden unexpl.death, syncope, hypertens., ven.thromboembol., laryngospasm, aspirat.pneumon., oropharyng./laryngospasm, aspirat.pneumon., pancreatit., dysphag., diarrh., abdom./stomach discomf., jaund., hepatit., hepat.fail., incr.ALT/AST/GGT/alkaline phosphat., rash, photosens.react., alopec., hyperhidros., rhabdomyolys., myalg., musculoskelet.stiffn., urin.incontin./retent., neonat.drug withdraw.syndr, priapism, temp.regulat.disord, chest pain, periph.oed., incr./fluct.bld.gluc., glycosylate.haemoglob., creatin.phosphokin.

Special warnings and precautions: *Monit.pt.clos.as clinic.improvem.may take sev.days to wks., monitor.high risk pts.for suic.,script smallest dose to reduce overdos.risk., known CV/cerebrovasc.dis., condits.predispos.to hypo-/hypertens., identify all poss.risk facts.for VTE bef. & dur.treatm.& undertake preventat.meas.as reqd.,poss.orthostat.hypotens., famil.hist.of QT prolongat., consid.dos.reduct./discont.if S&S of tard. dyskines.devel.,reduc.dos.& monitor closely if extrapyramid.S&S, discont.all antipsychot.meds.if S&S of neurolept.malign.syndr.develop/unexpl.high fev.without addit.clin.manifestats.of NMS, seiz.disord.hist./assoc.condit., condits/concom.meds.contrib.to elev.core body temp., incr.fatalit.(prim.CV/infect.) report.in elderly with dement.-relat.psychos., not indicat.for dement.-relat.psychos., monit.diab.mellit.for worsen.control & observ. pts.with diab.risk fact., weight gain usually where risk fact.pres.& in adolesc., aspirat.pneum.risk pts.as associat.with oesophag.dysmotil.& aspirat., monit.for impuls./compuls.behav./urges.consid.dos.reduct./discont., concom.stimul in ADHD pts, lower start.dose.in pts with high fall risk, contains lactose, safety in pregnan.& lactat not est., excret.in human milk.*

Interactions: *Concom.CNS act.meds and alcoh. due to prim.CNS effs.poss.antihypertens.effs. enhanc. due to α 1-adrenerg.recept. antagon., caut. with concom. meds.known to cause QT prolongat./electrol.imbal., AUC incr.by quinidine & poss.other potent CYP2D6 inhibits.(eg.fluoxetine/paroxetine), ketoconazole/other potent CYP3A4 inhibits(eg.itraconaz. & HIV prot.inhib.)/CYP2D6 poor metabol.incr plasma expos., carbamazepine/other potent CYP3A4 induc.(eg.rifampic./rifabut./phenytoin/phenobarb./primid./efavir./nevirap./St.John's wort) decr.plasma expos., concom.serotonerg.meds.eg SSRIs/ SNRIs /meds known to incr plasma conc. may incr risk of seroton.syndr.*

ALONZA, Accord [P/5]

Olanzapine.

Indications: Psychot.disords., pos.& neg.sympts.of schizophr., ac.episod.of mod.-sev.mania & prev.of recur.manic/ depress.episod.of bipolar.disord.

(\$5) TABS, 49/2.6.5/0035, 0036, 0037

3005269-001: 2.5 mg, 28, **R281,38**

3005270-001: 5 mg, 28, **R260,84**

3005271-001: 10 mg, 28, **R312,83**

Dosage: Psychot.disords: Admin.as once-a-day dos. Init: 5-10 mg/day with target dos.of 10 mg/ day within several days. Dos.incr.should occur at interv.of not less than 1 wk. Dos. range: 5-20 mg/day. Incr.dos over routine dly dos of. 10 mg only aft.clinic.assessm.

Ac.man.in bipol.disord: Init.10 mg/day. Dos. adjustm. if indicat.within range of 5-20 mg/day at interv.of not < 24 hrs.

Prev.recurr.in bipol.disord: Recomm. start. dos: 10 mg/day. Pts.already receiv. treatm. should cont.at same dos.to prev. recurr. Incr.dos.to above start.dos. within range of 5-20 mg dly only aft.clinic assessm. & at interv.of not < 24 hrs.

Safety of dos.above 20 mg/day not est. Grad.taper dos.when discont.

Contraindications: Known narrow-angl.glaucom. risk, safety & eff.not est.in childr.und.18 yrs.

Side effects: Freq: Eosinophil., leukopen., neutropen., hypotens., orthostat.hypotens., abnorm.gait, akathis., dizzin., dyskines., fall, hallucinat., parkinsonism, somnol., asthen., fatig., oed., pyrex., anticholinerg. eff.incl.constip, dry mouth, elevat.ALT/AST, high creat.phosphokin., high gamma glutamyl transf. high uric acid., incr.alkal.phosphat.elev.plasma prolact. lvl., incr.appetite, elev.cholester. elev. glucos.lvl. elev.triglicer.lvl. glycosur., peripher.oed., weight incr., arthralg., decr.libido, erect.dysfunc., pneumon., rash. Less freq: thrombocytopen., hypersens., diab.developm./-exacerb., diabet. ketoacidosis, diabet.coma, hypotherm., seiz., dyston., tard.dyskines., amnes, dysarthr., stutter., restless leg syndr., NMS, disont.sympts, bradycard., QTc prolong., ventr. tachycard.,fibril., sudden death, thromboembol., epistax., abdom.disten., pancreatit., hepatit., photosens., alopec., rhabdomyolysis., urin. incontin./-retent./-hesitat., amenorrh., breast enlargm., glactorrh., gynaecomast., priapism., incr.tot.bilirub. Freq. unknown: DRESS, neonat.drug withdraw.syndr.

Special warnings and precautions: Monit.pts.first several days-weeks as improv.of pts.clinic.cond.may take time, grad.discont.poss.cholinerg.syndr.within week., elev.prolact.lev.persist.modestly dur.chron.admin.with incr.in mammary gland neoplasms in rodents thought to be prolactin mediat., discont.if any clinic. NMS manifestat./high fev.observ., consid.discont./dos.reduct.if tard. dyskines.S&S develop, tard. dyskines. risk incr.with long-term expos., monit. exist.diab.mellit.for worsen. gluc.contr.& pts with risk fact., fast.bld. gluc.if hyperglycaem.develops, some pts.req. continuat. of anti-diabet. treatm.despite discont., elderly as post. hypotens. infreq.observ., hist.of seiz./ condits. assoc.with low.seiz.thresh., pts.exper. condit.contribut.to elevat.core body temp.(dehydrat./expos.extrem. heat/ stren. exerc.),.prostata.enlargem., narr.angle glauc., paralyt.ileus & relat. condits., CV dis.pts./ unstabl.heart dis./ conduct.abnorm./ HF/ cerebrovasc. dis./ other condits.predispos.to hypotens.due to orthostat.hypotens.risk, elev.ALT/AST & hepat.func.impairm./ pre-exist. condits. assoc.with limit. hepat.funct. reserve/ concom. potent. hepatotox. meds.consид. dos.red., predispos.risk fact.in elderly with dementia (>80 yrs/ sedat./concom benzodiaz./ pulmonary. condits.), card. vasc.adverse events incl.stroke/TIA in elderly dement.pts., not for dementia-related psychos./ Parkinson's, pts with Alzheimer's dement.poss.incr.riskof aspirat.pneumon./ seiz., reports of sudden card.death., pts with low leucocyte/neutrophil counts., hist.of meds.induc.bone marrow depress./ toxic., bone marrow depress., hypereosinophil.condits., myeloproliferat. dis., concom.meds.known to incr.QTc interv.esp.in elderly/ congenit. long QT syndr./CHF/heart.hypertrophy/ hypokalaem./ hypomagnesaeum., identify & prevent VTE risk fact., monit. dyslipidem.pts., early therap.for suicide risk, contains lactose.

Interactions: Antagon.dopamine agonists e.g. levodopa, concom. valproate incr.side eff., alcoh./ diazepam/ other CNS depress.have add.CNS depress. eff & poss.orthostat. hypotens., concom.products incr. QTcinterval., may enhanc. effs.of cert.antihypertens., CYP1A2 inhib.e.g. fluvoxamine/ ciprofloxac./ ketoconaz. decr.clear., reduc.bioavail.with activat.charc., fluoxetine incr.conc.& decr. clear., metabol.poss. induc.by smok.& carbamazepine.

ARIDUS, Zydus [P/S]

Aripiprazole

Indications: Schizophren. & maint.of clinic. improvem. in adults, ac.manic episod.assoc.with Bipol.1 disord., prevent.of recurr.new manic episod. in pts.exper.predomin.manic episod.& who respond.to Aridus treatm..

(S5) ORO DISP.TABS, 47/2.6.5/1039, 1040

3003431-001: 10 mg, 30, [R339,50](#)

3003440-001: 15 mg, 30, [R499,50](#)

Dosage: **Schizophren:** Recomm.start.dos.10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Dos.range: 10-30 mg/day. Enhanc.effic.at dos.high.than recomm. 15 mg/day not demonstrat. Indiv.pt.may benef. from high.dos. Max.dly.dos.not to exceed 30 mg/ day.

Bipol.mania: Recomm.start.dos.15 mg once dly. as monother./combin.ther. Indiv.pt.may benef.from high.dos. Max.dly.dos.not to exceed 30 mg.

Prevent.of recurr.manic episod.in bipolar I: Cont. ther.at same dos. Consid.dly.dos.adjustm. incl.dos.reduct.on clinic.status. Depress. episod. prevent. with monother. not est. Consid. clinic. appropr.supplem.ther.for prevent./treatm.of depress.episod.

Concom.meds: With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual dos. Incr.dos.when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc: Double dos. Addit.dos. incr. bas.on clinic.eval. Dos.to be reduc.when concom. CYP3A4 induc. withdr.

Contraindications: **Safety & effc.** in pts.und.18 yrs.not est.

Side effects: Freq: Diab.mellit., insomn., restlessn., anx., headache, dizzin., akathis., somnol., sedat., trem., extrapyramid. disord., blurr. vis., tachycard., orthostat. hypotens., N&V, dyspeps., constip., saliv.hypersecret., stomach discomf., musc.skelet.stiffn., asthen., fatig. Less freq: Hyperprolactinem., hyperglycaem., depress., hypersex., NMS, tard.dyskines., seiz., dyston., diplop., hiccups, periph.oed. Post market: Leucopen., neutropen., thrombocytopen., allerg. react., anaphylact.react., angioed., diabet. ketoacidosis., diabet.hyperosmol. coma, anorex., hyponatraem., suic. attempt/ideat./-complet., pathologic. gambling, impuls.contr.disords., poriomani., aggress., agitot., nervoun., grand mal convuls., seroton.syndr., speech disord., oculogyric crisis, QT prolongat., ventric.dysrhythm., sudd.unexplain. death, card.arrest, torsade de pointes, bradycard., syncope, hypertens., ven. thromboembol., laryngospasm, aspirat.pneumon., oropharyng.sp., pancreatit., dysphag., abdom. discomf., jaund., hepatit., hepat. fail., rash, photosens. react., alopec., hyperhidros., rhabdomyolys., myalg., musculoskelet.stiffn., urin. incontin./retent., neonat.drug withdraw.syndr, priapism, temp.regulat.disord, chest pain, incr. ALT/AST/ GGT/alkaline phosphat., incr.creatine phosphokinase/ bld.gluc./ incr. glycosylat.Hb, bld gluc.fluctuat.

Special warnings and precautions: Monit.pt. clos.as clinic. improvem.may take sev.days to wks., monit.high risk pts.for suic., known CV/ cerebrovasc. dis., condits.predispos.to hypotens., identify all poss.risk facts.for VTE bef.& dur. treatm. & undertake preventat. meas.as reqd., famil.hist.of QT prolongat., consid.dos. reduct./discont.if sympt.of tard.dyskines.devel., dos. reduct. & monit.if extrapyramid.sympts.appear, discont.all antipsychot.meds.if S&S of neurolept. malign.

syndr.develop/unexpl.high fev.without addit. clin. manifestats.of NMS, seiz.dos.hist./ assoc. condit., incr. fatalit. (prim.CV/infect.) report. in elderly with dement.-relat.psychos., not indicat. for dement.-relat. psychos., safety & effc.not est. in pts.>65 yrs., monit.diab. mellit.for worsen. control & observ.pts.with diab.risk fact., weight gain usually seen where risk fact.pres., aspirat. pneum. risk pts.as oesophag.dysmotil.& aspirat. report., monit.for impuls.contr.disords.& consid. dos.reduct./discont., concom.stimul in ADHD pts., condits/concom.meds.contrib.to elev.core body temp., falls risk, phenylketonur., do not use in pregn. or lactat., excret.in human milk, eval. effs. bef.driv./perform.complicat.tasks

Interactions: Poss.antihypertens. effs.enhanc.due to α 1-adrenerg. recept. antagon., concom.CNS act. drugs and alcoh.due to overlap.advers. effs., caut. with concom. meds.known to cause QT prolongat./ electrol.imbal., AUC incr.by quinidine & poss.other potent CYP2D6 inhibits.eg.fluoxetine/paroxetine, AUC & C_{max} incr.by ketoconazole/other potent CYP3A4 inhibits/CYP2D6 poor metabol, decr.AUC & C_{max} with valproate/carbamazepine/other potent CYP3A4 induc., concom. serotonerg. meds.such as SSRIs/SNRIs may incr risk or seroton.syndr.

ARIPRAZOLE MYLAN, Mylan [P/S]

Aripiprazole

Indications: Schizophren. & maint.of clinic. improvem. in adults, ac.manic episod.assoc.with Bipol.1 disord., prevent.of recurr.new manic episod. in pts.exper.predomin.manic episod.& who respond.to Abipiprazole Mylan ther.

(S5) TABS, 48/2.6.5/1191; 1192; 1193

3004213-001: 5 mg, 30, [R240,64](#)

3004214-001: 10 mg, 30, [R402,79](#)

3004215-001: 15 mg, 30, [R681,65](#)

Dosage: Recomm.start.dos.10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Dos.range: 10-30 mg/day. Enhanc.effic.at dos.high.than recomm. 15 mg/day not demonstrat. Indiv.pt.may benef. from high.dos. Max.dly.dos.not to exceed 30 mg/ day.

Bipol.mania: Recomm.start.dos.15 mg once dly. as monother./combin.ther. Indiv.pt.may benef.from high.dos. Max.dly.dos.not to exceed 30 mg.

Prevent.of recurr. manic episod.in pts: Cont. ther.at same dos. Dly.dos.adjustm. incl.dos.reduct. to be consid.on clinic.status. Depress. episod. prevent. with monother.has not been est. Consid. clinic. appropr.supplem.ther.for prevent./treatm.of depress.episod.

Concom.meds: With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual dos. Incr.dos.when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc: Double dos. Addit.dos. incr. based on clinic.eval. Dos.to be reduc.when concom. CYP3A4 induc.is withdr.

Contraindications: **Safety & effc.** in pts.und.18 yrs.not est.

Side effects: Freq: Diabet.mellit., insomn., restlessn., anx., akathis., trem., extrapyramid. disord., headache, somnol., sedat., dizzin., blurr. vis., N&V, dyspeps., constip., saliv.hypersecret., fatig. Less freq: Hyperprolactinem., hyperglycaem., depress., hypersex., tard.dyskines., dyston., diplop., tachycard., orthostat. hypotens., hiccups. Freq.unknown: Leukopen., neutropen., thrombocytopen., allerg.react., anaphylact.react., angioed., diabet.ketoacidosis., diabet.hyperosmol. coma, weight gain/decr., anorex., hyponatraem., pathologic.gambling, impuls.contr.disords., suic. attempt/ ideat., suicide complet., poriomani., aggress., agitot., nervoun., NMS, grand mal convuls., seroton.syndr., speech disord., oculogyric crisis, QT prolongat., ventric.dysrhythm., sudd. unexplain.death, card.arrest, torsade de pointes, bradycard., syncope, hypertens., ven. thromboembol., laryngospasm, aspirat. pneumon., pancreatit., dysphag., abdom./stomach discomf., diarrh., jaund., hepatit., hepat.fail., incr. ALT/AST/ GGT/alkaline phosphat., rash, photosens. react., alopec., hyperhidros., rhabdomyolys., myalg., stiffn., urin.incontin./retent., neonat.med. withdraw. syndr, priapism, temp.regulat.disord, chest pain, periph.oed., incr.creatine phosphokinase/ bld.gluc., bld gluc.fluctuat., incr. glycosylat.haemoglobin.

Special warnings and precautions: Monit.pt. clos.as clinic. improvem.may take sev.days to wks., monit.high risk pts.for suic., known CV/ cerebrovasc. dis., condits.predispos.to hypotens. incl. hypovolaem./treatm.with antihypertens., hypertens.incl.accelerat./malign., identify all poss.risk facts.for VTE bef.& dur.treatm.& undertake preventat. meas.as reqd., famil.hist.of QT prolongat., consid.dos. reduct./discont.if sympt.of tard.dyskines.devel., dos.reduct.& monit.if extrapyramid.sympts.appear, discont.all antipsychot.meds.if S&S of neurolept.malign. syndr. develop/unexpl.high fev.without addit. clin. manifestats.of NMS, seiz.disord.hist./ assoc. condit., incr. fatalit. (prim.CV/infect.)report.in elderly with dement.-relat.psychos., elderly pts., not indicat. for dement.-relat. psychos., monit.diab. mellit./high risk pts.for worsen.control & monit. reg., reduc.dos.in cas.of clinic.signif.weight gain., oesophag. dysmotil.& aspirat.assoc.with antipsychot. drug use theref.care in aspirat.pneum. risk pts., monit.for impuls.contr.disords.& consid. dos.reduct./discont., concom. stimul in ADHD pts., falls risk, laxat. eff.from mannitol, do not use in pregn. or lactat., excret.in human milk, eval. effs. bef.driv./perform.complicat.tasks

Interactions: Poss.antihypertens. effs.enhanc.due to α 1-adrenerg. recept. antagon., concom.CNS act. drugs and alcoh.due to overlap., CNS effs., caut. with concom. meds.known to cause QT prolongat./ electrol.imbal., AUC incr.by quinidine & other potent CYP2D6 inhibits.incl.fluoxetine/paroxetine, AUC & C_{max} incr.by ketoconazole/other potent CYP3A4 inhibits, decr.AUC & C_{max} with valproate/ carbamazepine/ other potent CYP3A4 induc., concom. serotonerg. meds.such as SSRIs/SNRIs may incr risk or seroton.syndr.

ARIZOFY, Sandoz [P/S]

Aripiprazole

Indications: Schizophren. & maint. of clinic. improvem. in adults, ac.man.episod.assoc.with bipol.I disord., prev.of recur.of new manic episod. in pts.predomin.exper.man.episod & who respond. to Arizofy treatm.**(S5) TABS** 46/2.6.5/0874, 0875, 0876723961-001: 5 mg, 30, [R233,10](#)723962-001: 10 mg, 30, [R390,00](#)723963-001: 15 mg, 30, [R660,00](#)**Dosage:** Schizophren: Recomm.start.dos.10 or 15 mg/day with maint.dos.of 15 mg/day once dly. Dos.range: 10-30 mg/day. Enhanc.effic.at dos.high.than recomm. 15 mg/day not demonstrat. Indiv may benef.from high.dos. Max.dly.dos.not to exceed 30 mg/day.**Manic episod.in Bipol.I disord:** Recomm.dos.15 mg once dly.as monother./combinat.ther. Some pts.may benef.from high.dos. Max.dly.dos.not to exceed 30 mg/day.**Recurr.prev.of manic episod.in Bipol.I disord:** Cont.ther.at same dos.for pts.who have been receiv.aripiprazole. Adjust dos.incl.dos.reduct.to be consid.on clinic.status. Prev.of depress.episod.use aripiprazole monther.not est. Consid.supplem.ther. for prev./treatm.of depress.episod as clinic. appropri.**Concom.meds:** With concom.potent CYP3A4/ CYP2D6 inhibits: Half usual dos. Incr.dos.when CYP3A4/CYP2D6 inhibit.withdr. With concom. potent CYP3A4 induc: Double dos. Addit.dos. incr.based on clinic.eval. Dos.to be reduct.to recomm.dos.when concom.CYP3A4 induc.is withdr.from combinat.ther.**Side effects:** Freq: Diab.mellit., restlessn., anx., insomn., headache, dizziness, akathisia, sedation, somnolence, tremor, extrapyramidal disorder, blurred vision, orthostatic hypotension, N&V, constipation, dyspepsia, salivary hypersecretion, asthenia, fatigue. Less freq: Hyperprolactinaemia, hyperglycaemia, depression, hypersexuality, tard dyskinesia, seizure, dystonia, restless leg syndrome, diplopia, tachycardia, hiccups. Freq.unknown: Leucopenia, neutropenia, thrombocytopenia, allergic reactions, diabetes, ketoacidosis, diabetic hyperosmolality, hyponatraemia, weight gain, decreased weight, anorexia, agitation, nervousness, suicide attempt/ideation/commitment, pathological gambling, impulse-control disorders, binge eating, compulsive shopping, parietal mania, weigths, NMS, speech disorder, grand mal convulsions, serotonin syndrome, oculogyric crisis, QT prolongation, ventricular arrhythmia, sudden unexplained death, cardiac arrest, torsades de pointes, bradycardia, syncope, hypertension, venous thromboembolism, aspiation pneumonia, oropharyngeal spasm, laryngospasm, pancreatitis, dysphagia, abdominal discomfort/stomach, diarrhoea, hepatitis, jaundice, increased ALT/AST/SGPT & alkaline phosphatase, liver failure, rash, photosensitivity, alopecia, hyperhidrosis, Dresser's syndrome, rhabdomyolysis, myalgia, musculoskeletal stiffness, urinary retention/ incontinence, neonatal medication withdrawal syndrome, priapism, temperature regulation disorder, chest pain, peripheral oedema, increased creatinine, phosphokinase/blood glucose/glycosylated haemoglobin, fluctuating blood glucose.**Special warnings and precautions:** Safety & efficacy in patients under 18 years, monitoring. Patients should be closely monitored as clinical improvement may take several days to weeks, monitoring high risk patients for suicide, prescribing small quantities to reduce overdose risk, known cardiovascular conditions predispose to hypotension. include hypovolaemia/treatment with antihypertensives, hypertensive acceleration/malignancy, identify all possible risk factors for VTE before and during treatment and undertake preventative measures as required, family history of QT prolongation, consider dose reduction/discontinuation if symptoms of tard dyskinesia develop, consider dose reduction and monitoring if extrapyramidal symptoms observed, discontinue all antipsychotic medications if S&S of neuroleptic malignant syndrome develop/unexplained fever without additional clinical manifestations of NMS, seizure disorder history/association condition, increased fatality (primarily CV/infectious) report in treatment elderly patients with psychoses related to Alzheimer's disease, in fixed dose trial significant dose response relationship for cerebrovascular adverse reactions, not indicated for dementia-related psychoses, observe for S&S of hyperglycaemia, monitoring diabetic mellitus/high risk patients for worsening control and do fast blood glucose for patients develop hyperglycaemia symptoms, hyperglycaemia may resolve on discontinuation but instantaneous may require continued anti-diabetic therapy, observe risk patients for clinical relevance weight gain and consider dose reduction if clinical significance, oesophageal dysmotility & aspiration associated with antipsychotic drug use therefore care in aspiration pneumonia risk patients, observe for development of pathological gambling & other impulse control disorders & consider dose reduction/discontinuation if present, concomitant ADHD medications, patients at high risk of falls, elevated core body temperature conditions include concomitant anticholinergics/dehydration lactose intolerance & possible effect on diabetic mellitus glycaemia control, safety in pregnancy and lactation not established, do not administer in pregnancy as concerns risks from animal reproductive studies & extrapyramidal/withdrawal symptoms in newborn infants exposed during 3rd trimester, excretion in human milk, evaluate effects before driving/performance of complex tasks**Interactions:** Certain antihypertensive effects possible enhancement, possible overlapping adverse effects with alcohol & other CNS medications, caution with concomitant medications known to cause QT prolongation/electrolyte imbalance, AUC increase by quinidine & possible other potent CYP2D6 inhibitors eg fluoxetine/paroxetine, AUC & C_{max} increase by ketoconazole & possible other potent CYP3A4 inhibitors, in CYP2D6 poor metabolisers concomitant strong CYP3A4 inhibition may result in high plasma concentration, moderate increase in concentration with concomitant diltiazem (weak CYP3A4 inhibitor) & escitalopram (weak CYP2D6 inhibitor), decreased AUC & C_{max} with carbamazepine/ other potent CYP3A4 inducer & valproate, possible serotonin syndrome with other serotonergic medications/medications known to increase aripiprazole concentration.**AROQUET, Accord [P/S]**

Quetiapine hemifumarate

Indications: Schizophren., manic episod.assoc.bi-polar disord.for which safety & effic.beyond 12 wks.not demonstrat.**(S5) TABS** 47/2.6.5/0633, 0634, 0635, 06363003597001: 25 mg, 100, [R249,42](#)3003598001: 100 mg, 90, [R421,64](#)3003600001: 200 mg, 60, [R437,08](#)3003601001: 300 mg, 60, [R534,47](#)**Dosage:** Admin.twice dly.Schizophren: Adults: Total dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day.

Adj.dos.in some pts.within 150-750 mg/day range depend.on clinic.response & tolerability.

Manic episod.assoc.bipol.disord: Total dly.dos. for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Further dose adjustment upto 800 mg/day by day 6 in increments of no greater than 200 mg/day. Adjust dose according to clinical response. & tolerability with range of 200-800 mg/day. Usual effect dose.: 400-800 mg/day.

Elderly: Init.25 mg/day, thereafter increase dose daily in increments of 25-50 mg to an effect dose.possible lower than young patients.

Contraindications: Safety in pregnancy & lactation not established, safety in advanced liver & renal impairment not established, safety & efficacy in children & adolescents below 18 years not established, co-administration of cytochrome P450 3A4 inhibitor eg. (HIV protease inhibitor/azole antifungal agents/ erythromycin & clarithromycin.)**Side effects:** Freq: Decreased haemoglobin, leucopenia, decreased neutrophil count, eosinophilia, increased hypersensitivity, hyperprolactinaemia, decreased T4 & increased TSH, increased serum triglyceride level, increased total cholesterol, decreased HDL, increased appetite, blood glucose increase to hyperglycaemia. level, abnormal dreams, nightmares, mania, suicidal ideation & behaviour, dizziness, dysarthria, somnolence, extrapyramidal symptoms, blurred vision, palpitation, tachycardia, orthostatic hypotension, dyspnoea, dry mouth, constipation, dyspepsia, vomiting, elevated ALT & gamma-GT level, asthenia, peripheral oedema, withdrawal symptoms, headache, irritability, pyrexia, weight gain. Less freq: Rhinitis, agranulocytosis, anaemia, thrombocytopenia, decreased platelet count, neutropenia, decreased T3, hypothyroidism, inappropriate antidiuretic hormone secretion, hyponatraemia, hyperglycaemia, diabetes, pre-existing diabetes exacerbated, metabolic syndrome, somnambulism, sleep related eating disorder & talk, restless leg syndrome, seizure, tard dyskinesia, syncope, bradycardia, QT prolongation, venous thromboembolism, dysphagia, pancreatitis, intestinal obstruction/ileus, elevated AST, angioedema, SJS, rhabdomyolysis, urinary retention, sexual dysfunction, priapism, galactorrhoea, breast swelling, menstrual disorder, NMS, hypothermia, elevated blood creatinine/ phosphokinase. Freq.unknown: Anaphylactic reaction, stroke, hypertension, hyperventilation, respiratory alkalosis, acute respiratory failure, abdominal pain, jaundice, hepatitis, toxic epidermal necrolysis, erythema multiforme, drug-rash with eosinophilia & systemic symptoms, neonatal drug withdrawal/ syndrome.**Special warnings and precautions:** Possibility of worsening of depression & emergence of suicidal ideation/self-harm in bipolar disorder, monitoring patients especially during early therapy & dose change for clinical worsening & suicidal risk persist until significant remission occurs, observe same precaution as those for other psychiatric disorders, careful monitoring of patients at great risk eg. those with suicide related events history/ exhibitionist suicidal ideation prior to therapy initiation, taper dose with discontinuation, monitoring glucose concentration of existing diabetes/ hyperglycaemia symptom in those at risk, fast blood glucose test advised for those develop hyperglycaemia symptom during therapy, continued anti-diabetic medications possible necessity despite therapy discontinuation, metabolic parameter to be assessed before initiation treatment & change continuation, increased extrapyramidal symptom incidence, consider discontinuation if tard dyskinesia S&S occur, known CV disorder/ other conditions predispose to hypotension, seizure history, discontinuation if symptom of neuroleptic malignant syndrome occur, severe neutropenia sometimes fatal in risk patients & patients without risk factor, discontinuation therapy if neutrophil count < 1.0 x 10⁹/litre, fever/infection symptom to be reported especially without predisposing factor, weight change/weight gain/ lipid change/elderly patients with intestinal obstruction/ileus, QT prolongation family history, concomitant medications known to increase QT interval/concomitant neuroleptic especially in patients with increased QT prolongation risk, cardiomyopathy/ myocarditis, possible dose adjustment with phenytoin/other concomitant hepatoenzyme inducer, not for use in elderly with dementia exhibit behaviour disturbances, low effect dose in elderly when considered essential, patients at risk for aspiration pneumonia, comparison to placebo elderly patients with dementia-related psychoses at increased risk of death, elderly with Parkinson's disease, concomitant grapefruit juice not recommended, VTE risk factor identification before & during therapy, gallactose intolerance, renal/hepatic impairment, concomitant antihypertensives or cause electrolyte imbalance, concomitant anticholinergics, sleep apnoea**Interactions:** Other CNS acting drugs & alcohol possible aggravation primary CNS effects, increased clearance with concomitant thioridazine/ carbamazepine/ phenytoin/ other hepatoenzyme inducer, significant increase in quetiapine AUC with ketoconazole, serum concentration possible increase with grapefruit juice, antihypertensive effects of antihypertensive medications enhanced.**AROQUET XR, Accord [P/S]**

Quetiapine fumarate

Indications: Schizophren., prev.relapse in stable schizophren.pts.maint.on AROQUET XR, bipol. disord. incl.manic/depress.episod.assoc. with bipol.disord., recurr.prev.in maint.treatm.of bipol. disord. as monother./combin.with a mood stabil., maj. depress.disord., relapse prevent.in stabil. maj. depress.disord. pts.maint.on AROQUET XR.**(S5) PROLONG-REL. TABS** 48/2.6.5/0011, 52/2.6.5/0998, 48/2.6.5/0012, 0013, 00143003727001 50 mg, 60, [R366,77](#)3003728001 150 mg, 30, [R187,01](#)3003732001 200 mg, 60, [R760,40](#)3003733001 300 mg, 60, [R863,26](#)3003734001 400 mg, 60 [R814,32](#)**Dosage:** Admin.once daily. Do not split, chew/ crush. Missed dose: Take as soon as possible but do not take double dose.

Adults: Schizophren: Daily dose: Day 1: 300 mg, Day 2: 600 mg. After day 2 upto 800 mg. Adjust dose within effect dose range of 400-800 mg/day depend on clinical responses & tolerance.

dysphag., poss.ingest.food aspirat., N&V, constip., hepatit., cholest.jaund., ac.pancreatit., skin reacts., urin.incont./retent., interstit.nephrit., benign hypertherm., sudd.unexpl.death. Unknown freq: Poss.fatal agranulocytos., granulocytopen

Special precautions: Limit ther.to sev.ill pts. non-respons./intol.to classic neurolept.ther., fatal agranulocytos.risk, close medic.supervis.advis. when init.ther.as collapse poss.accompan.by card. &/resp.arrest more likely to occur dur.init.titrat.in assoc. with rapid dos.escalat., seiz.hist./other predispos. fact.as dos.poss.import. seiz.predict.incr. with high.dos., low.dos.if seiz.occure & init. anti-convuls. ther.if necess., monit.gluc.contr.of exist. diab./hyperglycaem.sympt.of those at risk, fast. bld.gluc.test.if hyperglycaem.sympt.develop, contin.anti-diab.meds.poss.necess.despite ther. discont., concom.meds.with anticholinerg./hypotens./resp.depress.effs., monit.recurr.psychot. sympt.if abrupt discont.necess., outweigh benef./risk.in prim.bone marrow disorders, monit. WBC if infect./fev./sore throat/flu-like sympt. report., norm.WBC count bef. init.ther.thereaft. wkly.WBC/ANC monit.dur.1st 18 wks. & at least 2 wkly thereafter.throughout.treatm.& for 1 mnth. aft. discont., discont.immed.if WBC < 3 000/mm³ &/neutroph.count <1 500/mm³ & do not re-expos. pts. refer.to haematology.if furth.WBC drop exper., concom. myelosuppress.meds.

Drug interactions: Enhanc.CNS eff.of alcoh./ MAOI's/ CNS depress., incr.haematolog.effs.with carbamazepine, incr.circulat.collapse with resp. depress./ arrest risk with concom./recent treatm. with benzodiazepin./other psychotrop., cimetid./ erythromycin may incr.plasma lev., poss.chang.in plasma lev.of Clozapine/other agents which bind strongly to prot.e.g. warfar., incr.neurolept. malign. syndr.risk with Li./other CNS act.agents., poss. pharmacokinet.interact.with anticonvuls.agents.

DOPAQUEL, Dr Reddy's [P/S]

Quetiapine fumarate

Indications: Schizophren., manic episod.assoc.bi-polar disord.for which safety & effc.beyond 12 wks.not demonstrat.

(S5) TABS. 43/2.6.5/0429, 0430, 0431, 0432

716050-003: 25 mg, 14, [R36,68](#)

716050-001: 25 mg, 100, [R262,33](#)

716051-002: 100 mg, 14, [R69,44](#)

716051-001: 100 mg, 90, [R446,72](#)

716052-002: 200 mg, 14, [R112,14](#)

716052-001: 200 mg, 60, [R480,85](#)

716053-002: 300 mg, 14, [R131,15](#)

716053-001: 300 mg, 60, [R562,05](#)

Dosage: Admin.twice dly.

Schizophren: Adults: Tot.dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day.

Adj.dos.in some pts.within 150-750 mg/day range depend.on clinic.response & tolerab.

Manic episod.assoc.bipol.disord: Tot.dly.dos. for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Furth.dos.adjustm upto 800 mg/day by day 6 in increm.of no great.than 200 mg/day. Adjust dos.accord.to clinic.respon. & tolerabil.with range of 200-800 mg/day. Usual effect.dos.: 400-800 mg/day.

Elderly: Init.25 mg/day, thereafter.incr.dos.dly.in increm.of 25-50 mg.to an effect.dos.poss.low.than young.pts.

Contraindications: Safety.in pregn.& lactat.not est., safety.in advanc.liv.& ren.impairm.not est., safety & effc.in childr.& adolesc.bel.18 yrs.not est., co-admin.of cytochrome P450 3A4 inhibit.eg. (HIV prot.inhibit./azole antifung.agents/ erythromyc. & clarithromyc.), quetiapine/excipient hypersens.

Side effects: Somnol., dizzin., dry mouth, asthen., constipat., tachycard., orthostat.hypotens., dyspeps., weight gain., syncope, neurolept. malign. syndr., leucopen., neutropen., periph.oed., bld. dyscras., hypersens.incl.anaphylax., hyperglycaem. sometim. extreme assoc.with ketoacidosis./coma/ death, diab.mellit./pre-exist.diab.exacerb., hyperprolactinaem., hypothyroid., inappropri.ADH secret., CNS effs., headache, syncope, anx., extrapyramid. sympt., dysarth., seiz., tard. dyskines., restless legs syndr., dry eyes, asymptomat. chang.in eye lens.with longt.use, blurr. vis., ear/chest/back pain, card./menstr. /psych. disord., QTc interv. prolongat., ven. thromboembol., dyspn., rhinit., pancreatit., GI disturbs. incl.intest. obstruct./ileus, jaund., hepatit., skin reacts.incl.Stev.John.syndr./tox. epiderm.necrolys./erythema multiforme, angioed., myalg., rhabdomyolys., UTI, urin.retent., priapism, galactorrh., sex.dysfunct., breast swell., periph. oed., ac withdr.sympt., fev., hypotherm., elev.ser.transamin./cholester./triglycerid., decr.in thyroid horm. lev., akathisis, accident.inj.esp.elderly, agranulocytos., dysphag.

Warnings and special precautions: Poss. worsen. of depress.& emerg.of suic.ideal./self-harm in bipol.disord., monit.pts. esp.dur.early ther. & dos. chang.for clinic.worsen.& suicidal., risk persist. unt.signif.remiss.occurs, observ.same precaut. as those for other psych.disord., caref. monit.of pts.at great.risk eg.those with suic.relat. events hist./ exhib.suic.ideal.prior to ther.init., taper dos.with discont., monit.gluc.contr.of exist.diabet./ hyperglycaem. sympt.in those at risk, fast.bld.gluc.test.advis.for those develop. hyperglycaem. sympt.dur.ther., cont.anti-diab. meds. poss.necess.despite ther.discont., metabol. paramet.to be assess. bef.init.treatm.& chang. contr., incr.extrapyramid.sympt.incid., cons. discont. if tard.dyskines.S&S occur, known CV dis./ other condits.predispos.to hypotens., seiz.hist., discont. if sympt.of neurolept.malign.syndr.occure, sev. neutropen.somet.fatal in risk pts. & pts. without risk fact., discont.ther.if neutroph.count < 1.0 x 10⁹/lit., fev./infect.sympt.to be report.escp. without predispos.fact., monit.weight gain/lipid chang./elderly/pts.with intest.obstruct./ileus, QT prolong.family hist., concom.meds.known to incr. QT interv./concom.neurolept.escp.in pts.with gain.in QT prolong.risk, cardiomyopathy/myocardit., poss. dos.adjustm.with phenytoin/other concom.hepat. enzyme induc., not for use in elderly with dement. exhibit.behav. disturbs., low.effect.dos.in elderly when consid. essent., pts.at risk for aspirat. pneum., concom. grapefruit juice not recomb., VTE risk fact. identif.bef.& dur.ther., galact.intol., ren./ hepat.impairm., concom.antihipertens.or caus. electrol.imbal.

Interactions: Other CNS act.drugs & alcoh.poss. aggrav.prim.CNS effs., act.of dopaminerg. antagonis., incr. clear.with concom. thioridazine/ carbamazepine/ phenytoin/ other hepat.enzyme induc., signif.incr.in quetiapine AUC with ketoconazole, ser.conc.poss.incr.with grapefr. juice.

GEODON, (Viatris Healthcare) Upjohn [P/S]

Ziprasidone

Indications: Ac.exacerb., & maint.of clinic. improvem. dur.continuat.ther.in schizophren.

(S5) CAPS, 32/2.6.5/0584, 0585, 0586, 0587

703465-001: 20 mg, 60, [R1 330,11](#)

703468-001: 40 mg, 60, [R1 393,94](#)

703475-001: 60 mg, 60, [R1 871,63](#)

703476-001: 80 mg, 60, [R2 289,48](#)

Dosage: Admin.with food.

Adults: Recomm.init.dos: 40 mg 2xdly. Adjust accord. to clinic.respons.up to max.80 mg 2xdly. Max.dly.dos. may be reach.as early as day 3.

(S5) IM INJ, 36/2.6.5/0478, 36/34/0479

Indications: Ac.agitat.in schizophren.where rapid control reqd.

703467-001: 20 mg/ml, 1 vial+dil., [R189,98](#)

Dosage: IM inj.when oral formulat.inappropri. Reconstit.only with water for inj. If long term ther. necess.switch to oral formulat. ASAP. Admin.for >3 consec.days not stud.

Adults: Recomm.dos: 10-20 mg as reqd.to max. 40 mg /day. 10 mg dos.maybe rep.every 2 hrs. Init. dos.of 20 mg may be reqd.which maybe follow.by furth.10 mg dos.aft.4 hrs.thereaft. 10 mg dos.every 2 hrs.to max.40 mg/day.

Contraindications: Inj.in elderly (>65 yrs), do not mix.with other meds/solv., known QT interv. prolongat., congenit./acquir.long QT syndr., meds. known/observ.to prolong.QT interv., rec.MI, uncompens.HF, card.dysrhythm.treat. with Class I A & III anti-dysrhythm.drugs, pregn.& lactat., safety & effc.in childr.und.18 yrs.not eval., safety & effc.in CV dis.not est.

Side effects: Mild to mod.prolongat.of QT interv. & torsades de pointes, neurolept.malign. syndr., tard.dyskines.with long.term.ther., sedat., akathisia, extrapyramid.disord., dizzin., rhinit., incr. appetite, hypocalcaem., psych.disord., CNS effs., dyston., Parkinsonism, gen.ton.clon.seiz., tard. dyskines., dyskines., drooling, atax., dysarthr., oculogyric cris., attent.disturb., hypersomn., hypoaesthes., paraesthes., lethargy, torticoll., paresis., akines., hyperton., restless leg syndr., lymphopen., palpitat., tachycard., bradycard, blurr. vis., photophob., amblyop., vis.disturbs., eye prurit., dry eyes, vertigo, tinnit., ear pain, vasodilat., hypertens. cris,hypertens., orthostat.hypotens., hypotens., postur.hypotens., dyspn., sore throat, hiccups, GI disturbs., saliv. hypersecret., dysphag., swell. tong., skin reacts., drug react.with eosinoph.& system.sympts.-acne, psorias., alopec., face swell., musc.-skelet. rigidity/discomf., musc.cramp, extremity pain, joint stiffn., trismus, enures., urin.incontin., dysur., erect.dysfunct., erection incr., priapism, galactorrh., gynaecomast., asthen., headache, fatig., chest discomf., gait abnorm., thirst, pain, feel.hot, pyrex., hepat.enzyme incr., bld.lact. dehydrogen. incr., eosinophil., loc.reacts.for inj.,laryngismus, sweat., allerg.reacts., man., hypoman., flu syndr., angioed., facial weakn., serotonin syndr

Warnings and special precautions: Teratogen. in anim., low ser.K&Mg to be replet. bef.init.treatm., monit electrol wth diuret.ther., risk of further QTc prolongat.& dysrhythm.incr.with persist.prolong QTc interv.& not clear if rout.ECG screen.effect.detect., avoid in signif.CV illn.hist., discont.if QTc measurem. persist.>500 msec., eval.sympts.indicat.of torsades de pointes, discont.if neurolept.malign. syndr. devel. with S&S of tard.dyskines.consider. discont./ dos. reduct., seiz.hist., clos.monit.of high risk sulc.pts., concom.CNS drugs & drugs act. on dopaminerg.& serotonerg.syst., caps. cont.lact., breast feed.not advis., given CNS effs. concom. central act.agents incl.alcoh.& meds. act. on dopaminerg.& serotonerg.systs., appropri. meth.of contracept.in women of child-bearing potent, elderly, imp.ren.funct.for inj., low.dos.in mild to mod.hepat.impairm., exper.lack.in sev. hepat. insuffic., discont.if sev.cut.anadv.react. occur, not approv.for elderly dement.relat. psychos.

Drug interactions: Effs.of dir.& indir.dopamine agonists poss antagon., ketoconaz.potent CYP3A4 inhibit.incr.AUC & C_{max}.expos. carbamazepine decr.ziprasidone expos.

MYLAN QUETIAPINE, (Mylan) Xixia [P/S]

Quetiapine.

Indications: Schizophren., manic episod.assoc. with bi-polar disord. for which safety & effc. beyond 12 wks. not demonstrat.

(S5) TABS. 41/2.6.5/0951, 0952, 0954, 0955

716668-001: 25 mg, 100, [R254,00](#)

716670-001: 100 mg, 90, [R432,90](#)
716671-001: 200 mg, 60, [R465,58](#)
716672-001: 300 mg, 60, [R544,20](#)
Dosage: Adults: Admin.twice dly.

Schizophren: Tot.dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day. Adjust.dos.within 150-750 mg / day range depend.on clinic.response & tolerab.

Bipol.disord.assoc.manic episod: Tot.dly.dos. for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Furth.dos.adjustm. up to 800 mg/day by day 6 in increm.of no great. than 200 mg/day. Adjust dos.accord.to clinic. respon. & tolerabil.with range of 200-800 mg/ day. Usual effect.dos.: 400-800 mg/day.

Elderly: Init.25 mg/day, theraft.incr.dly.dos.in increm. of 25-50 mg.to an effect.dos.poss.low. than young.pts.

Contraindications: *Safety in pregn. & lactat. not est., safety & effic.in childr. & adolesc.und. 18 yrs. not est., safety in advanc.liv.& ren. impair. not est., not indic.for elderly pts.with dement.exhibit.behav.disturbs., co-admin.with azole antifung./macrolide antibiot./HIV prot. inhibits., Lapp-Lact.defic., gluc-galact. malabsorpt.*

Side effects: *Hyperglycaem.sometimes extreme assoc. with ketoacidosis/hyperosmol.coma/death, bld.disords., hypersens.reacts.incl.anaphylax., Stev.John.synedr., diab.mellit./exacerbat.of pre-exist.diab., psych.disords., somnol., dizzin., headache, anx., syncope, extrapyramid.sympt., seiz., tard.dyskines., neurolept.malign.synedr., dry eyes, blurr.vis., eye lens chang.with longterm use, ear/abdom./back/chest pain, tachycard., QTc prolongat., orthostat.hypotens.esp.dur. init.dos.titrat., hypertens., ven.thromboembol., rhinit., dry mouth, constip., dyspeps., diarrh., jaund., hepatit., myalg., UTI, priapism, galactorrh., asthen., periph. oed., ac.withdr. sympt., fev., weight gain., elev. ser.transamin./ cholesterol & triglyceride, decr.thyroid horm.leve.*

Special precautions: *Elderly esp.dur.init. dos.per., monit.gluc.contr.of exist.diabet./ hyperglycaem.sympt.in those at risk, pts.who develop.hyperglycaem.sympt.dur.ther.should undergo fast.bld.gluc.test, cont.anti-diab.meds. poss.necess.despite ther.discont., low.effect.dos. in elderly when consid.essent. & caref.monit., benef.monit., risk assessm.in elderly pts.tak.stroke risk into account, known CV/cerebrovasc.dis./ condits. predispos.to hypotens., consid.dos. reduct./discont.ther.if tard.dyskines.S&S occur, discont.ther. & admin.appropr.treatm.in case of neurolept.malign.synedr., concom.alcoh./other central.act.meds., concom. antihypertens./meds. prolong.QTc interv., poss.dos.adjustm.with phenytoin/other concom.hepat.enzyme induc., reduc.dos.with non-induc.eg.sod.valproate, caref. assessm.of indiv.pt.in case of cont.treatm.at high. dos., seiz.hist., withdr.grad., ren./hepat. impairm.*

Drug interactions: *Act.of dopaminerg. antagon., incr.clear.with concom. carbamazepine/ phenytoin/thioridazine, signific. incr.in quetiapine AUC with ketoconazole.*

NEZOLAP, Macleods [P/S]

Olanzapine

Indications: *Psychot.disorders., ac.episod of mod.to sev.mania & prevent.recurr.manic episod.in bipol.disord.*

(S5) ORODISPERS.TABS, 48/2.6.5/0483, 0484

3005326-001: 5 mg, 30, [R371,80](#)

3005327-001: 10 mg, 30, [R475,09](#)

(S5) FILM-COAT.TABS, 47/2.6.5/0284, 0285, 0286

3003671-001: 2.5 mg, 30, [R235,00](#)

3003672-001: 5 mg, 30, [R289,00](#)

3003673-001: 10 mg, 30, [R345,00](#)

Dosage: Dissolv.orodisp.tab.in mouth.Take full glass of water immed.aft.admin.OR dispers.in glass of water/ suit.liq.immed bef.admin.The 10 mg orodisp.tab.may be halv.at break line.

Psychot.disorders: Admin.as sngl.dly.dos.Init. 5-10 mg/day with target dos.of 10 mg/day within sever.days.Do not consid.dos.incr.bef.1 wk.Dos. range from 5-20 mg/day.

Dos.incr.over 10 mg/day advis.only aft.clinic.assessm.

Ac.man.in bipol.disorders: Admin.as sngl.dly.dos.gener.start.with 10 mg.Dos.adjustm.with.dos. range of 5-20 mg/day if indic.should occur at interv.of not less than 24 hrs.

Prevent.recurr. of man.in bipol.disord: Recomm.start.dos: 10 mg/day.For those receiv. Nezapol for man.episod.cont.ther.for prevent.recurr.at same dos.Incr.dos.over 10 mg with.range of 5-20 mg/day advis.only aft.clinic.assessm.& should occur at interv.of not less than 24 hrs.Safety of dos.above 20 mg/day not eval.Improvem.in clinic. condit.poss.take sever.days/wks.

Contraindications: *Known narrow-angl.glauca.risk, S&E in childr.<18 yrs.not est., safety in pregn.& lactat.not est., effic.in elderly pts.with dement.-relat.psychos.not est.*

Side effects: *Freq.: Eosinophil., neutropen., leucopen., periph.oed, weight gain, elev. cholest./glucose/, triglycerid., glucosur, incr. appet., dizzin., akathis., somnol., parkinson., abnorm.gait, falls, hallucin., speech disord., tremor, tachycard., orthostat.hypotens., dry mouth, constip., incr.ALT/AST, arthralg., erectile dysfunct., decr.libido in males/females, asthen., fatig., oedema, pyrex., ALT/ SGPT incr., AST/ SGOT incr., prolact.incr., incr.alkal.phosphat., high creatine phosphokin., high GGT., high uric acid. Less freq: Thrombocytopen., hypersens., developm./ exacerbat.diabet.occas.associat. with ketoacidosis/ coma, hypotherm., seiz., dystonia, tard.dyskines., amnes., dysarth., stutter., restless legs syndr., neurolept.malign.synedr., discontinuat.sympts., bradycard., ven. thromboembol., QTc prolong., ventric.tachyc./ fibrillat., sudden death, thromboembol., epistaxis, pneumon., pancreatit., abdomin.distens., hepatit., rash, photosens.reacts., alopec., DRESS, rhabdomyolys., urinary incont./ retent./ hesitat., priap., amenorrh., gynaecomast./ breast enlarg.in males, neonat.drug withdraw.synedr., breast enlarg., galactorr., incr.total bilirub.*

Special warnings and precautions: *Period.assessm. advis.for maint.treatm. & contin.at low.dos.need.to maint.remiss., pass.into breast milk, discont.grad., elev.prolact.lev.dur.chron.admin., discont.if any clinic.NMS manifestat./ high fev.observ., seiz.hist./ condits.assoc.with seiz.thresh.low., consid.dos.reduct./ discont.if tard.dyskines. S&S devel., longt.high-dos.ther., elderly, hepat.impairm., pre-exist.condits.assoc.with liv.impairm., concom. hepatox.meds., per.LFT in signif.hepat.dis., elderly pts.with dement.-relat.psychos., pts.≥ 80 yrs., concom.benzodiazepin./ other centr.act.agents & alcoh., pulm.condits., monit.exist.diab.for worsen.gluc.contr./ pts.at risk for diab.mellit.developm., monit.pts.start.treatm.at risk of diab.for hyperglycaem.sympt.in which case to undergo fast.bld.sugar test., some pts.req. contin.of anti-diabet.treatm.desp.ther.discont., monit.pts.regul.for lipids eg.baseline/ 12 wks after start & every 5 yrs.thereaft., concom. meds.incr.QTc interv.esp.elderly/ congenit.long QT syndr./ CHF/ card.hypertrophy/ hypokalaem./ hypomagnesaem., risk facts for ven. thromboembol., orthostat.hypotens.risk in card.pts., concom.BP lower. meds.other than alpha-1 adrenerg.antagon., symptomat. prostat.enlargem., paralyt.ileus & relat. condits., rec.MI, unstab.card.dis., aspirat.pneum. risk, not recommend.in Parkinson.dis.due to poss.incr.in parkinson.sympt. & hallucinat., condits.contrib.to elev.core body temp., supervis.suicide risk pts., discont.ther.if hepatit.diagn., low leucocyte &/ neutroph. count, meds.-induc.bone marr.depress./toxic.hist., bone marr. depress.caus by concom.illn./ radiat.-/ chemother., hypereosinophil.condits.with myeloproliferat. dis., phenylketonuria, activ.charcoal admin.2 hrs.bef./ aft.Nezolap, concom.fluoxetine not recomm., consid.low.start.dos.with fluvoxamine/ other CYP1A2 inhib.*

Interactions: *May antagon.effs.of levodopa & dopamine agonists, poss.enhanc.effs.of cert.antihypertens., pharmacokinet.affect.by subst. induc./ inhib./ act.as substr.to isoenzym.CYP1A2, poss.antagon.effs.of direct. /indir.dopamine agon., metab.poss.induc.by smok. & carbamazepine, reduc.bioavail.with activat.charc., CYP1A2 inhibit.incl.fluvoxamine reduc.clear., fluoxetine incr.conc. & decr.clear.*

OLAWIN, (Sanofi-Aventis) Winthrop [P/S]

Olanzapine

Indications: *Psychot.disorders., ac.episod of mod.to sev.mania & prevent.recurr.manic episod.in bipol. disord.*

(S5) ORODISPERS.TABS, [P/S] 44/2.6.5/9854, 9855

721386-001: 5 mg, 30, [R285,32](#)

721390-001: 10 mg, 30, [R365,97](#)

(S5) FILM-COAT.TABS, [P/S] 44/20.6.5/1020, 1021

721388-001: 5 mg, 30, [R280,51](#)

721389-001: 10 mg, 30, [R359,78](#)

Dosage: Dissolv.orodisp.tab.in mouth. Take full glass of water immed.aft.admin.OR dispers.in glass of water/suit.liq.immed bef.admin. The 10 mg orodisp.tab.may be halv.at break line.

Psychot.disorders: Admin.as sngl.dly.dos. Init. 5-10 mg/day with target dos.of 10 mg/day within sever.days. Do not consid.dos.incr.bef.1 wk. Dos. range from 5-20 mg/day.

Dos.incr.over 10 mg/day advis.only aft.clinic.assessm.

Ac.man.in bipol.disorders: Admin.as sngl.dly.dos. gener.start.with 10 mg. Dos.adjustm.with.dos. range of 5-20 mg/day if indic.should occur at interv. of not less than 24 hrs.

Prevent.recurr. of man.in bipol.disord: Recomm. start.dos: 10 mg/day. For those receiv. Olawin for man.episod.cont.ther.for prevent.recurr. at same dos.Incr.dos. over 10 mg with.range of 5-20 mg/day advis.only aft.clinic.assessm.& should occur at interv.of not less than 24 hrs. Safety of dos. above 20 mg/day not eval. Improvem.in clinic. condit.poss.take sever.days/wks.

Contraindications:*known narrow-angl.glauca. risk, safety & effic. in childr.und.18 yrs.not est., safety in pregn. & lactat. not est., effic.in elderly pts.with dement.- relat.psychos.not est.*

Side effects: *Cholinerg. syndr.poss.with discont., neurolept.malign.synedr., treatm.emerg.dyskines., seiz., hyperprolactinaem., hyperglycaem.somet. assoc.with ketoacidosis/hyperosmol.coma or death, bld.dyscras., allerg./skin react., weight gain, elev. cholest./gluc./triglycer./ALT/AST lev., incr.appet., glucosur., diab.exacerbat., hypotherm., CNS effs., dizzin., akathis., parkinson., dyston., bradycard., QTc prolong., ventr.tachycard./fibrillat., sudd. death, orthostat.hypotens., thromboembol., GI disturbs., pancreatit., hepatit., alopec., rhabdomyolys., urin.diffic., priapism, galactorrh., asthen., fatig., oed., oesophag. dysmotil./aspirat., CV adverse events in elderly pts.with dement.-relat. psychos.*

Special precautions: *Effectiven.for long.than 6 wks.not est.in control.stud., lact.intol., per. assessm. advis.for maint.treatm. & contin.at low. dos.need.to maint.remiss., pass.into breast milk, discont.grad., elev.prolact.lev.dur.chron.admin., discont.if any clinic.NMS manifestat./high fev. observ., seiz.hist./condits.assoc.with seiz.thresh. low., consid.dos.reduct./discont.if tard.dyskines. S&S devel., longt.high-dos.ther., elderly, hepat. impairm., pre-exist.condits.assoc.with liv.impairm., concom. hepatox.meds., per.LFT in signif.hepat. dis., pts.≥ 80 yrs., concom.benzodiazepin./other centr.act. agents & alcoh., pulm.condits., monit. exist. diab.for worsen.gluc.contr./pts.at risk for diab. mellit.developm., monit.pts.start.treatm.at risk of diab.for hyperglycaem.sympt.in which case to undergo fast.bld.sugar test., some pts.req. contin. of anti-diabet.treatm.desp.ther.discont., concom. meds.incr.QTc interv.esp.elderly/ congenit. long QT syndr./CHF/card.hypertrophy/ hypokalaem./ hypomagnesaem., concom.BP*

lower. meds.other than alpha-1 adrenerg. antagon., symptomat. prostat.enlargem., paralyt. ileus & relat. condits., rec.MI, unstab.card.dis., aspirat. pneum. risk, condits.contrib.to elev.core body temp., supervis.suicide risk pts., discont.ther.if hepatit. diagn., low leucocyte &/neutroph.count, meds.induc.bone marr.depress./toxic.hist., bone marr. depress.caus.by concom.illn./radiat./chemother., hyper eosinophil.condits.with myeloproliferat. dis., activ.charcoal admin.2 hrs. bef./aft.Olanwin, concom.fluoxetine not recomb., consi.d.low.start.dos.with fluvoxamine/other CYP1A2 inhib.

Drug interactions: May antagon.effs.of levodopa & dopamine agonists, poss. enhanc.effs.of cert. antihypertens., pharmacokinet.affect.by subst. induc./inhib./act.as substr.to isoenzym. CYP1A2, poss.antagon.effs.of direct./indir.dopamine agon., reduc.plasma conc.with valproate, incr.trem. incid./dry mouth/weight gain/incr.appet.with Li/valproate, metab.poss.induc.by smok.& carbamazepine, reduc.bioavail.with activat.charc., CYP1A2 inhibit.incl.fluvoxamine reduc.clear., fluoxetine incr.conc.& decr.clear.

OLEANZ, Ranbaxy [P/S]

Olanzapine.

Indications: Psychot.disords., ac.mania episod., prev.recurr.manic episod.of bipol.disord.

(S5) TABS, 43/2.6.5/0326, 0327, 0328

715994-001: 2,5 mg, 28, [R325,08](#)

715995-001: 5 mg, 28, [R278,84](#)

715996-001: 10 mg, 28, [R334,32](#)

(S5) RAPITABS, 43/2.6.5/0069, 0070

715967-001: 5 mg, 28, [R710,27](#)

715968-001: 10 mg, 28, [R910,62](#)

Dosage: Recomm.continuat.at low.dos.need.to maint.remiss.in respond.pts. Take immed.aft. open. placing in mouth/disperse in water/ beverage.

Psychot.disorders: Admin.once dly. Init. 5-10 mg/ day with target dos.of 10 mg/day within several days. Dos. incr.should not be consid.bef.1 wk.of ther. Dos.rang.from 5-20 mg as snlgl.dly.dos. Dos. incr.above 10 mg advis.only aft.clinic.assessm. Consid.5 mg start.dos.for hepat.impairm./elderly.

Ac.man.in bipol.disord: Recomm.dos: 10 mg once dly. Dos.adjustm.within range of 5-20 mg/ day to occur at interv.of not less than 24 hrs.if indicat.

Prev.recurr.in bipol.disord: Recomm.init.dos: 10 mg/ day. For those receiv.Oleanz for manic episod.cont. ther.at same dos. Incr.dos.over 10 mg advis.only aft.clinic.assessm.& should occur at interv.of not less than 24 hrs. Safety of dos.above 20 mg/day not est.

Contraindications: Known narrow-angl.glauca risk, safety in pregn.& lactat.& pts.und.18 yrs.not est., pts.with dement.-relat.psychos., concom. fluoxetine not recomb., not recomb.in Parkinson's dis.

Side effects: Hyperprolactinaem., neurolept. malign. syndr., seiz., tard.dyskines., incr.CVA effs. incl.stroke/fatalit., hyperglycaem.incl.keto-acidos./hyperasmol.coma/death, bld.dyscras., allerg. reacts.incl.anaphylact., periph.oed., hypercholesterolaem., hypertriglyceridaem., hepatit., pancreatit., personal.disord., mood/ ment. chang., hallucinat., agitac., akathis., dizzin., somnol., abnorm.gait, falls, anx., hostilit., euphor., nervoun., trem., Parkinsonism, symptomatol., speech disord., dyskines.incl. buccogloss. syndr./choreoathetos., dyston., resid. effs. incl.movem.disord., myoclon., twitch., drowsin., headache, apathy, confus., insomn., stutter., paraesthes., hyperton., water intoxic., abnorm. vis., diplop., brady-/tachycard., ventric. extrasyst., palpitac., orthostat.hypotens., hypertens., ven.thromboembol., pneum., incr. cough, pharyngit., dyspn., rhinit., GI disturbs., rash, acne, dry skin, photosens., sweat., asthen., extremit./ joint pain, rhabdomyolys., urin.incont., vaginit., dysmenorrh., priapism, menstr.chang., decr. libido, weight chang., fev., chest pain, flu-like sympt., incr.salivat., thirst, angio-/fac.oed., discontinuat. react., exacerbat.of pre-exist.diab.

Special precautions: Effectiven.for more than 6 wks not est., period.re-assesm.to determ.need for maint. treatm., discont.grad., elev.prolact. lev.persist. modestly dur.chron admin., incr. mammary gland neoplasms in rodents consid. prolact. mediat., discont.if any clinic.NMS manifestat./high fev.observ., seiz.hist./condits. assoc. with seiz./low.seiz.thresh., consid.discont. / dos.reduct.if tard.dyskines.S&S develop, tard. dyskines.risk incr.with longt.expos.& sympt.can deterior./arise aft.treatm.discont., elev.AST&/ALT lev., S&S of hepat.impairm., pre-exist. condits. assoc with limit.hepat.funct.reserve, concom. potent.hepatotox.meds., period. assessm. of transaminas.recomm.in hepat.dis. pts., discont.treatm.if hepatit.diagn., incr.diab. preval.in schizophren.pts., monit.exist.diab.for worsen. gluc.contr., monit.pts.start.treatm.at risk of diab.for hyperglycaem.sympt., fast.bld.gluc.if hyperglycaem.develops, some requir.contin.anti-diabet.treatm.despite Oleanz discont., predispos. risk fact.in elderly, smokers, dos.modific.necess. in cases where olanzapine metab.slow., concom. meds.known to incr.QTc interv./congenit.long QT syndr./CHF/card.hypertrophy/hypokalaem.& hypomagnesaem., admin.concom.activ.charc.at least 2 hrs.bef./aft., monit.pts.on concom. carbamazepine/omeprazole/rifampicin, pts. receiv. meds. that low.BP by mechanisms other than alpha-1 adrenerg.antagon., subst.inhibit./ induc.CYP1A2 isoenzyme, incr.hallucinat.in Parkinson's pts., symptomat.prostat.enlargem., narrow-angl.glauca., paralyt.ileus/relat.condits., rec.MI hist., unstab.heart dis., card.pts., cont. aspartane, reg.BP monit.of pts.>65 yrs., leucopen./ neutropen., meds.induc.bone marrow depress./toxic., bone marrow depress.caus.by concom. illn./radium ther./chemother., hyper eosinophil. condits., myeloproliferat.dis., condits.contrib.to core body temp.elev., aspirat. pneumon.risk as oesophag.dysmotil.& aspirat. assoc.with antipsychot., monit.high risk suic.pts., predispos.risk fact.in elderly with dement.relat. psychos.to incr.mortality incl. >80 yrs./sedat./ concom. benzodiazepines & pulm.condits., elderly with dement.taking stroke risk into account.

Drug interactions: CNS eff.enhanc.of other CNS depress.& alcoh., may antagon.effs.of levodopa & dopamine agonists, poss.neutropen. with valproate, may enhanc.effs.of cert. antihypertens., QTc prolongat.risk with meds. known to cause QTc prolongat., pharmacin.effs. with subst.that induc./inhib.CYP1A2, activat. charc. reduc.bioavail., fluoxetine incr.conc.& decr.clear., smok./carbamazepine/omeprazole & rifampicin.low.plasma lev., potent.CYP1A2 inhibit.poss.decr.clear.

OLEXAR, Cipla-Medpro [P/S]

Olanzapine.

Indications: Psychot.disords.(incl.schizophren.), ac.mod.to sev. mania, prev.recurr.of manic/ depress. episod.of bipol.disord.

(S5) TABS, 37/2.6.5/0316, 0317, 0318

715657-001: 2,5 mg, 30, [R314,82](#)

715658-001: 5 mg, 30, [R375,00](#)

715659-001: 10 mg, 30, [R495,00](#)

Dosage: Admin.as once-a-day dos. Safety of dos. above 20 mg/day not eval.

Psychot.disorders: Init. 5-10 mg/day with target dos.of 10 mg/day within several days. If indic. dos.adjustm.of 5 mg increm/decrem.should occur at interv.of not less than 1 wk. Dos.range: 5-20 mg once dly. Incr.above routine 10 mg/day advis.only aft.clinic.assessm.

Ac.man.in bipol.disord: Init.dos:10 mg once dly. Dos.adjustm.within range of 5-20 mg/day to occur at interv.of not less than 24 hrs.if indicat.

Prev.recurr.in bipol.disord: Recomm.init.dos: 10 mg/ day. For those receiv.Olexar treatm.for manic episod.cont.ther.at same dos. Incr.dos.to great.than recomb.start.dos.within range of 5-20 mg/day only aft.clinic.assessm.at interv.of not less than 24 hrs.

Contra-indications: Known narrow-angl. glauca. risk, safety in pregn.& lactat.& childr.und.18 yrs. not est., concom.fluoxetine not recomb.

Side-effects: Neurolept.malign. syndr., tard. dyskines., incr.incid.of abnorm.gait/falls/urin. incont.in./pneumon./death/CVA's incl.stroke in elderly with dement.relat.psychos., trans. elev.liv.transaminase plasma lev., bld.dyscras., weight gain, elev.prolact.& gluc.lev., water intoxicat., diab.mellit., acidos., hyponatraem./-kalaemia./-glycaem., hyperbilirubinaem./-cholesterolaem./-lipidaem./-uricaem., diab.acidos., goiter, ketosis, gout, hyperkalaem./-natraem., hypoproteinaem., albuminur., CNS effs.incl.seiz., neuropsych.disorders, hyperton., articulac.impairm., decr.libido, paraesthes., alcoh./tobacco misuse, withdr.syndr., taste pervers., incr.libido, fac. paralyis., incoordinat., nystagmus, neuropathy, encephalopathy, neuralg., eye disorders.incl.ocul. musc.abnormal.& lens.pigment deposits, deafn., ear pain, tinnit., orthostat.hypotens., CV disorders. incl.HF/card.arrest & pulm.embol, incr.cough, pharyngit., rhinit., dyspn., voice alterat., apnoea, aspirat.pneumon., pneumon., laryngit., hyperventilat., asthma, atelectas., epistax., haeoptys., hiccup, stridor, lung oed., hypoventilat., hypox., dysphag., GI disturbs.incl.intest.obstruct.& rect.haemorrh., tooth caries, periodont.abscess, oral monillias, gingivit., hepatit., sweat., rash, alopec., skin ulc./discolourat., seborrh., eczema, photosens.reacts., hirsutism, musc.-skeleton & connect.tiss.disorders, myasth., osteoporos., back-/bone pain, urin.disorders., UTI, urin.incontin., menstr.irreg., vaginit., abnorm.ejaculat., impot., priapism, breast pain, enlarg.uter.fibroids, vag. haemorrh., asthen., fev., dent.-/chest-/neck-/pelvic pain, fac.oed., hangover eff., intent.injury.

Special precautions: Monit.exist.diab.for worsen. gluc.contr., monit.pts.start.treatm.at risk of diab.for hyperglycaem., fast.bld.gluc.if hyperglycaem. develops, some pts.reg.continuat. of anti-diabet.treatm.despite discont., grad. discont., elev.prolact.lev.persist.modestly dur. chron. admin., hist.of seiz./condits.assoc.with seiz./low.seiz.thresh., predispos.risk fact.in elderly with dement.relat.psychos.to incr.mortality incl. >80 yrs./sedat./concom.benzodiazepines & resp.condits., S&S of hepat.impairm., pre-exist.condits.assoc. with limit.hepat.funct.reserve, concom. potent. hepatotox.meds., discont.if hepatit.diagnos., concom. centr.act.agents & alcoh., concom. meds. known to incr.QTc interv./congenit.long QT syndr./ CHF/card.hypertrophy/hypokalaem.& hypomagnesaem., symptomat.prostat.enlargem., narr.angle glauc., paralyt.ileus & relat.condits., card.pts./condits.predispos.to hypotens.due to orthostat. hypotens.risk, elderly with dement. and/Parkinson's dis., condits.contrib.to core body temp. elevat., pts.at risk of aspirat.pneum., monit. high risk suic.pts., leucopen./neutropen., meds. induc.bone marrow depress./toxic., bone marrow depress., hyper eosinophil.condits., myeloproliferat. dis., reg.BP monit.of pts.>65 yrs.

Drug interactions: May antagon.effs.of levodopa & dopamine agonists, may enhanc.effs.of cert. antihypertens., CYP1A2 induc.incr.clear.& CYP1A2 inhibit.reduc.clear., reduc.bioavail.with activat. charc., fluoxetine incr.conc.& decr.clear., metabol.poss.induc.by smok.& carbamazepine.

PREXOLAN, (Aspen Pharmacare: Pharma) Pharmacare [P/S]

Olanzapine

Indications: Managem.of psychot.disord. manifestat., ac.mania & prev.recurr.of manic/ depress. episod.of bipol.disord.

(S5) ORODISP.TABS (ODT), 44/2.6.5/0915, 0916

719806-001: 5 mg, 30, [R534,64](#)

719807-001: 10 mg, 30, [R685,25](#)

(S5) TABS, 43/2.6.5/0908, 0909, 0910

Indications: Managem.of schizophren. manifestat., ac.mod.to sev.mania episode & prevent. recurr.of manic/depress.episod.of bipol. disord.

720712-001: 2,5 mg, 30, [R411,20](#)

720713-001: 5 mg, 30, [R518,35](#)

720714-001: 10 mg, 30, [R673,95](#)

Dosage: ODT tabs: Place on tong/dispers.in water. Only remove from foil immed.bef.use.

Psychot.disorders: Init.5-10 mg/day with target dos.of 10 mg/day within sever.days. If indic.dos .adjustm.should occur proceed.at interv. of not less than 1 wk.

Ac.man.in bipol.disord: Init.dos:10 mg once dly. Dos.adjustm.within range of 5-20 mg/day to occur at interv.of not less than 24 hrs.if indicat.

Prev.recurr.in bipol.disord: Recomm.start.dos: 10 mg/ day. For those receiv. Prexolan treatm. for manic episod.cont.ther.at same dos. Incr.dos.to great.than recomm.start.dos.within range of 5-20 mg/day only aft. clinic.assessm.at interv.of not less than 24 hrs. Safety of dos.above 20 mg/day not eval. Improvem.in pt.condit.may take sev.days to wks.

Hepat.impairm./elderly: Consid.start.dos.of 5 mg

(S5) POWD.FOR SOL.FOR INJ. 43/2.6.5/0911

Indications: *Control of agitat./disturb.behav.in schizophren. & relat.psychos.and ac.man.assoc. with bipol.I disord.when oral ther.not appropri.*

720715-001: 10 mg, 1 vial, [R157,99](#)

Dosage: Reconstit.with ster.water for inj.only. IM use only. Do not admin IV or SC. Discont.IM treatm. and init. oral treatm.as soon as clinic. appropri. Admin.in healthcare facility. First est. respons. & tolerab.with oral olanzapine in pts. never admin.olanzapine bef.

Recomm.dos:10 mg as sngl.IMI. Bas.on indiv clinic. status a 2nd dos.of up to 10 mg 2 hrs.aft.1st inj.and 3rd inj.of up to 10 mg 4 hrs.aft.2nd inj.

If oral formulat.reqd.combin.tot.dos.of both formulat.not to exceed.max.oral dos.of 20 mg dly. Safety of tot.dly dos.great.than 30 mg not eval.

Contraindications: Known narrow-angl.glauc. risk, safety & effic.in childr.und. 18 yrs.not est.

Side effects: Freq: Eosinophil., weight gain, incr. appetite, personal.disord., hallucinat., somnol., dizzin., headache, akathis., Parkinson., dyskines., asthen., agitat., abnorm.gait, falls, trem., speech disord., amblyop., chest pain, orthostat.hypotens., periph.oed., rhinit., pneumon., dry mouth, constipat., trans.ALT & AST asymtmetat.elev., rash, urin.incontin., elev.prolact.lev. Less freq: Leucopen., thrombocytopen., neutropen., allerg. reacts., hyperglycaem., hypertriglyceridaem., diab. ketoacidosis., diab.coma, elev.cholester.lev., amnes., anx., euphor., hostility, imp.articulat., hyperton., movem.disord., nervousn., myoclon., insomn., stutter., extrapyramid.effs., seiz., dyston., bradycard., tachycard., QTc prolongat., ven. thromboembol., cough, pharyngit., abdom.pain, pancreatit., hepatit., photosens.react., alopec., extrem.pain, joint pain, rhabdomyolys., urin. hestitat., menstrual chang., priap., fev., fatig., oed., high creatine phosphokoin., incr.tot.billrub. Freq.unknown: Developm./exacerbat.of diab., tard.dyskines., neurolept.malign.syndr., discont. sympts., ventric.tachycard./fibrillat., sudd.death, incr.alkaline phosphokin.

Warnings and special precautions: Discont. grad., elev.prolact.lev.persist.modest.dur.chron. admin., incr.mammary gland neoplasms consid. prolact. mediat. mediat.report.in rodents on chron. antipsychot. medicat., discont.ther.if S&S of neurolept. malign.syndr./high fev.observ., consid. dos. reduct./discont.ther.if S&S of tard.dyskines. devel., monit.exist.diab.for worsen.gluc.contr., monit. pts.start.treatm.at risk of diab.for hyperglycaem., fast.bld.gluc.if hyperglycaem. devel., some pts.req.continuat.of anti-diabet. treatm. despite discont., seiz.hist./condits.assoc. with seiz./low.seiz.thresh., hepat.impairm./ concom. potent.hepatotox.meds., period. transamin. monit.in hepat.dis., pre-exist.condits. assoc.with limit.hepat.funct.reserv., discont.ther.if hepatit.diagn., elderly, cons.low.start. dos. in case of fact.decr.pharmacokinet.clear./incr.pharmacodyn. respons., not approv.in dement.-relat. psychos., condits.contrib.to elev.body core temp., monit. high risk suic.pts., symptom.prostat. enlargem., paralyt.ileus & relat.condits., card.dis., low leucocyte/neutroph.counts, meds.induc.bone marrow depress./toxic., bone marrow depress.aft. illn./radiat.& chemother., hyperosinophil.condits., myeloproliferat.dis., fact.that may slow metabol.of Prexolan, concom. CYP1A2 inhibit./induc., aspirat. pneum.risk, pre-exist.risk fact.for CVAE, eval.S/E bef.driv./perform.complicat.tasks, lact.intol., concom. BP low.meds.other than alpha-1 adrenerg. antagon., admin.activ.charcoal 2 hrs bef./aft. olanzapine, safety in pregn.& lactat.not est., period. assessm.advis.for maint.treatm.& cont.at low.dos.need.to maint. remiss., effic.for more than 6 wks.not est.in control.trials, cholinerg.syndr. poss. on discont., most ser.cases of symptomat. hypotens./ apnoea & ventric.tachydysrhythm.with IM use had temporal relationship to benzodiazepine use, ser.CV dis.where syncope/ hypotens./ bradycard.incr.medic.risk, period.BP monit.in pts.over 65 yrs., signs & sympts consist. with OD report.1-3 hrs.follow.IM admin., admin.inj. in healthcare facility with close monit.x3 hrs.post inj., IM admin.in CV risk pts.poss.incr.medic.risk, concom. parenteral olanzapine& benzodiazepine not recomm., if consid.necess.parenter. benzodiazep. to be admin.at least 1 hr.aft.IM olanzapine, if parenteral benzodiazep.already admin. IM olanzapine should only be consid.aft. caref.clinic. eval. & pt.to be caref.mont.for excess. sedat.& card. resp.depress., do not combin.inj.in same syringe as diazepam/ haloperidol, do not use lorazepam to reconstit inj., IMI cont.maltose

Interactions: Concom.centr.act.agents & alcoh., fluoxetine decr.clear., may antagon.effs.of levodopa & dopamine agon., may enhanc.effs.of cert.antihypertens., concom.meds.known to incr. QTc interv.esp pts with congenit.long QT syndr./ CHF/heart hypertrophy/hypokalaem.& hypomagnesaem., reduc.eff.with activat.charc., metabol. poss.induc.by concom.smok./ carbamazepine ther.low.plasma lev., clear.decr.by known potent CYP1A2 inhibit., concom.IM admin. with lorazepam adds to somnol.observ.

PSYQUET, Sandoz [P/S]

Quetiapine.

Indications: *Schizophren., manic episod.assoc. with bi-polar disord. for which safety & effic. beyond 12 wks. not demonstrat.*

(S5) TABS. 43/2.6.5/0446, 0849, 0850, 0851

718352-002: 25 mg, 30, [R76,20](#)

718352-001: 25 mg, 105, [R266,70](#)

718353-001: 100 mg, 90, [R435,60](#)

718354-001: 200 mg, 60, [R466,20](#)

718355-001: 300 mg, 60, [R544,20](#)

Dosage: Adults: Admin.twice dly.

Schizophren: Tot.dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day.

Adjust.dos.within 150-750 mg / day range depend.on clinic.response & tolerab.

Bipol.disord.assoc.manic episod: Tot.dly.dos. for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Furth.dos.adjustm.up to 800 mg/day by day 6 in increm.of no great.than 200 mg/day. Adjust dos.accord.to clinic.respon. & tolerabil. with range of 200-800 mg/day. Usual effect.dos.: 400-800 mg/day.

Elderly: Init.25 mg/day, thereaft.incr.dly.dos.in increm. of 25-50 mg.to an effect.dos.poss.low. than young.pts.

Contraindications: *Safety in pregn.& lactat. not est., safety & effic.in childr.& adolec.und.18 yrs. not est., safety in sev.liv.& ren.funct.impairm.not est., not indic.for elderly pts.with dement.exhibit. behav.disturbs., co-admin.with cytochrome P450 inhibitors., Lapp-Lact.defic., gluc-galact.malabsorpt.*

Side effects: Hyperglycaem.sometim. extreme assoc. with ketoacidosis/hyperosmol.coma/death, bld. disord., hypersens.reacts.incl.anaphylax., Stev. John.syndr., diab.mellit./exacerbat.of pre-exist. diab., psych.disord., somnol., dizzin., headache, anx., syncope, extrapyramid.sympt./ syndr., seiz., dry eyes, blurr.vis., eye lens chang. with longt.use, ear/back/chest pain, tachycard., QTc prolongat., postur.hypotens., hypertens., ven. thromboembol., rhinit., GI disturbs., weight gain, jaund., hepatit., rash, myalg., UTI, priapism, galactorrh., dysarthr., asthen., fev., periph.oed., elev.ser.transamin./cholesterol & triglyceride, decr. thyroid horm.lev., orthostat.hypotens.esp. elderly dur.init.dos.titrat., tard.dyskines., neurolept. malign.syndr., ac.withdr.sympt.

Special precautions: Known CV/cerebrovasc. dis./ condits.predispos.to hypotens.esp.elderly, monit.gluc.contr.of exist.diabet./hyperglycaem. sympt.in those at risk, pts.who devel. hyperglycaem. sympt.dur.ther.should undergo fast. bld. gluc.test,cont.anti-diab.meds.poss.necess. despite ther.discont., concom.antihypertens./ meds. prolong.QTc interv., concom.alcoh./other central. act.meds., hepat.cytochrome P450 enzym. induc., elderly esp.dur.init.dos.per., ren./hepat. impairm., consid.discont.ther.if tard.dyskines.S&S occur, seiz.hist., discont.ther.& admin.appropr. treatm. in case of neurolept.malign.syndr., withdr. grad., rebound psychos., reduc.dos.with non-induc. eg. sod.valproate.

Drug interactions: *CNS eff.of CNS depress.& alcoh. potent., antihypertens.eff.of antihypertens. poss. enhanc.with concom.use, act.of dopaminerg. antagon., incr.clear.with concom.carbamazepine/ phenytoin/ barbits./rifampicin/thioridazine.*

QUERO XR, Pharma Dynamics [P/S]

Quetiapine fumarate.

Indications: *Schizophren., prev.relapse in stable schizophren.pts.maint.on Quero XR, bipol. disord. incl.manic/depress.episod.assoc. with bipol.disord., recurr.prev.in maint.treatm.of bipol. disord. as monother./combin.with a mood stabil., maj. depress.disord., relapse prevent.in stabil. maj. depress.disord. pts.maint.on Quero XR.*

(S5) PROLONG.REL.TABS, A49/2.6.5/0280, 0281; 0282; 0283;0284

3003646-001: 50 mg, 60, [R440,12](#)

3003647-001: 150 mg, 60, [R446,28](#)

3003648-001: 200 mg, 60, [R910,90](#)

3003649-001: 300 mg, 60, [R927,30](#)

3003650-001: 400 mg, 60, [R974,45](#)

Dosage: Admin.once dly.. Do not split, chew/ crush. Miss.dos: Take as soon as poss. but do not take double dos.

Adults:

Schizophren: Dly.dos: Day 1: 300 mg, Day 2: 600 mg. Aft.day 2 upto 800 mg. Adjust dos.within effect.dos.range of 400-800 mg/day depend.on clinic.respons.& tol.

Manic episod.assoc.with bipol.disord: Init. dly. dos: Day 1: 300 mg, Day 2: 600 mg & up to 800 mg aft.day 2. Adjust.dos.within effect.dos. range of 400-800 mg/day depend.on clinic. respons. & tol.

Depress.episod.assoc.with bipol.disord: Admin. once dly.in even. Titr.as foll: Day 1: 50 mg, Day 2:100 mg, Day 3: 200 mg, Day 4: 300 mg. May be titr.to 400 mg on day 5 & up to 600 mg by day 8.

No addit.benef.seen with 600 mg group pts. dur. short-term treatm.

Recurr.prev.in maint.treatm.of bipol.disord: Pts. who have respond.well to Quero XR in combin. ther.with a mood stabil.for ac.treatm.of bipol. disord.should cont. at same dos. May be adjust. depend.on indiv.clinic.respons.& toler. within 400-800 mg/day dos.range.

Pts.respond. to Quero XR for ac.treatm.of bipol. disord. should cont.at same dos.regim. Dos.may be re-adjust. depend.on indiv.clinic.responses.& toler. within 300-800 mg/day dos.range.

Maj.depress.disord: Admin.once dly in even. Init. dos: Day 1 & 2: 50 mg incr. to 150 mg on day 3 & 4. Furth. adjustm. can be made upw.or downw. within recomm.dos.range of 50-300 mg depend.on clinic. respons.& toler. Maint.ther: Cont.with effect. dos.dur.init.treatm. Adjust dos.within recomm.dos.range depend.on clinic.responses.& toler.

Switch.from immed.rel.tabs: Switch to XR tabs.at equiv.tot.dly dos.tak.once dly.

Elderly: Init.50 mg/day. Incr.in increm.of 50 mg/ day to effect.dos.depend.on clinic.responses.& toler. In maj.depress.init.dly.dos.50 mg on days 1-3 incr.to 100 mg day 4; 150 mg on day 8 & then up to 300 mg depend.on clinic.respon.& tol.

Contraindications: Concom.P450 3A4 inhibit., safety in pregn.& lactat.not est., safety in childr.& adolesc.not est., safety in advanc.liv.& ren. impairm. not est.

Side effects: Freq: Decr.Hb, leucopen., hypersens., hyperprolactinaem., decr.T₄ & incr.TSH, incr.appetite, bld.gluc.incr.to hyperglycaem. lev., abnorm.dreams, nightmares, man., suicid.ideal & behav., dizzin., dysarthr., somnol., syncope, extrapyramid.sympts., blurr.vis., palpitat., tachycard., orthostat.hypotens., dyspn., rhinit., dry mouth, constipat., dyspeps., vomit., elev.ALt & gamma-GT lev., UTI, asthen., periph. oed., withdr.sympts, headache, irritabil., pyrex., weight gain. Less freq: Agranulocytos., anaem., eosinophil., thrombocytopen., decr.platel.count, neutropen., pancytopen., decr.T₃, hypothyroid., inappropri.antiuret.horm.secret., hyponatraem., hyperglycaem., diabet., pre-exist.diabet. exacerbat., metabol.syndr., somnambul., sleep relat.eat.disord.& talk., restless leg syndr., seiz., tard.dyskines., bradycard., QT prolongat., ven. thromboembol., dysphag., pancreatit., intestin. obstruct./ileus, elev.AST, angioed., Stev.John. syndr., rhabdomyolys., urin.retent., sex.dysfunct., priap., galactorrh., breast swell., menstr.disord., NMS, hypotherm., elev.bld.creatine/phosphokin./ gamma-GT lev./non-fast.ser.triglyceride & total cholesterol.

Freq.unknown: Anaphylact.react., stroke, hypertens., hyperventilat., resp.alkalos., ac.resp.fail., abdom.pain, jaund., hepatit., tox.epiderm.necrolys., erythema m ultiforme, drug-rash with eosinophil.& syst.sympts., neonat.drug withdr./syndr.

Warnings and special precautions: Hepat. impairm., safety & effic.in childr.& adolesc.not est., monit.gluc.contr.of exist.diabet./ hyperglycaem. sympt.in those at risk, cont.anti-diab. meds.poss.necess.despite ther.discont., caref.monit.for poss.suicide ideat., risk fact.for leucopen.& /neutropen.incl.pre-exist.low WBC/ drug induc.hist.thereof., pts.to report S&S consist. with agranulocytos./infect., managem.of metabol. paramet.reg.dur.treatm., elderly esp.init.due to orthostat.hypotens.& accid.injury risk, known CV/ cerebrovasc.dis.& other condit.predispos.to hypotens., seiz.hist., consid.dos.reduct./discont.if S&S of tard.dyskines.occur, do not incr.dos.if extrapyramid.sympts.exper., discont.if sympt.of neurolept. malign.syndr.occur, concom.meds. known to prolong QTc interv./fam.hist./risk fact.of QT prolongat., withdr.grad., sleep apnoea risk fact., concom.meds with anti-cholinerg.effs./urin. retent./signif.prostat.hypertrophy/intestin.obstruct.or relat.condits/incr.IOP/narr.angle glauc., aspirat. pneumon.risk, suspect.cardiomyopathy/myocardit., high.intestin.obstruct.risk & concom.meds.decr. intestin.motil., VTE risk fact., pancreatit.assoc.risk fact., alcoh./drug abuse hist., poss.dos.adjustm. with carbamazepine/phenytoin/other concom. hepat. enzyme induc., monit.weight gain, cont. lact., compar.to placebo elderly pts.with dement.-relat.psychos.at incr.risk of death, elderly with Parkinsons, reproduct.toxic.in anim.stud., caut.on ability to drive/operat.machin.

Interactions: CYP 3A4 inhibit.incr.quetiapine AUC, grapefruit juice not recomm., hepat.enzyme induc.decr.system.expos., caut.with other CNS act.meds./alcoh., & aniticholiner., incr.clear.with concom. thioridazine, meds.caus.electrol.imbal/ incr.QT interv.

QUESARA, Macleods [P/S]

Quetiapine fumarate

Indications: Schizophren., bi-polar disord.assoc.manic episod.for which safety & effic.beyond 12 wks.not demonstrat.

(S5) TABS., 47/2.6.5/0144, 0145,0146, 0147

3003781-001: 25 mg, 100, R165,00

3003782-001: 100 mg, 100, R480,00

3003782-002: 100 mg, 90, R432,00

3003783-001: 200 mg, 60, R463,94

3003784-001: 300 mg, 60, R544,00

Dosage: Adults: Admin.twice dly.

Schizophren: Tot.dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day.Adj.dos.in some pts.within 150-750 mg/day range depend.on clinic.response & tolerab.

Bipol.disord.assoc.manic episod: Tot.dly.dos.for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Furth.dos. adjustm. upto 800 mg/day by day 6 in increm.of no great.than 200 mg/day.Adjust dos.accord.to clinic.respon.& tolerabil.with range of 200-800 mg/ day. Usual effect.dos.: 400-800 mg/day.

Elderly: Init.25 mg/day, theraft.incr.dly.dos.in increm. of 25-50 mg.to an effect.dos.poss.low.than young pts.

(S5) XR TABS. 48/2.6.5/0076,0077, 0078,0079

Indications: Schizophren., prev.relapse in stable schizophren.pts.maint.on QUESARA XR, bipol. disord.incl.manic.episod.assoc. with bipol.disord., recurr.prev.in maint.treatm.of bipol. disord. as monother./combin.with a mood stabil.

3003537-001: 150 mg, 30, R223,14

3003540-001: 200 mg, 60, R760,40

3003541-001: 300 mg, 60, R863,26

3003542-001: 400 mg, 60, R974,45

Dosage: Admin.once dly.Do not split, chew/ crush. Miss.dos: Take as soon as poss. but do not take double dos.

Adults: **Schizophren:** Dly.dos: Day 1: 300 mg, Day 2: 600 mg. Aft.day 2 upto 800 mg. Adjust dos.within effect.dos.range of 400-800 mg/day depend.on clinic.responses.& tol.

Manic episod.assoc.with bipol.disord: Init. dly. dos: Day 1: 300 mg, Day 2: 600 mg & up to 800 mg aft.day 2. Adjust.dos.within effect.dos. range of 400-800 mg/day depend.on clinic. respons.& tol.

Recurr.prev.in maint.treatm.of bipol.disord: Pts. who have respond.well to QUESARA XR in combin. ther.with a mood stabil.for ac.treatm.of bipol. disord.should cont. at same dos. May be adjust. depend.on indiv.clinic.responses.& toler. within 400-800 mg/day dos.range.

Pts.respond. to QUESARA XR for ac.treatm.of bipol. disord. should cont.at same dos.regim. Dos.may be re-adjust. depend.on indiv.clinic.responses.& toler. within 300-800 mg/day dos.range.

Contraindications: Concom.P450 3A4 inhibit., safety in pregn.& lactat.not est., safety in childr.& adolesc.not est., safety in advanc.liv.& ren. impairm. not est.

Side effects: Freq: Decr.Hb, leucopen., decr.neutroph.count, eosinoph.incr.hyperprolactinaem., decr.T₄ & incr.TSH, decr.T₃, incr.serum triglyceride lev., incr.tot.cholester., decr.HDL, incr.appetite, bld.gluc.incr.to hyperglycaem. lev., abnorm.dreams, nightmares, suicid.ideal & behav., dizzin., dysarthr., somnol, extrapyramid.sympts., blurr.vis., palpitat., tachycard., orthostat.hypotens., dyspn., dry mouth, constipat., dyspeps., vomit., elev.ALt & gamma-GT lev., asthen., periph. oed., withdr.sympts, headache, irritabil., pyrex., weight gain., UTI, rhinit.Less freq.: Agranulocytos., anaem., hypersens, thrombocytopen., decr.platel.count, eosinophil., neutropen., angioed., anaphylact.react., hypothyroid., inappropri.antiuret.horm.secret., hyponatraem., hyperglycaem., diabet., pre-exist.diabet. exacerbat., metabol.syndr., somnambul., sleep relat.eat.disord.& talk., restless leg syndr., seiz., tard.dyskines., syncope, bradycard., QT prolongat., ven. thromboembol., dysphag., pancreatit., intestin. obstruct./ ileus, elev.AST, jaund., hepatit., SJS, rhabdomyolys., urin.retent., sex.dysfunct., priap., galactorrh., breast swell., menstr.disord., NMS, hypotherm., elev.bld.creatine/ phosphokin Freq.unknown: Anxiety, chest pain, stroke, hypertens., dry eyesabdom.pain, diarrh., TEN erythema multiforme, drug-rash with eosinophil.& syst.sympts., myalg., neonat.drug withdr./syndr., back/ ear pain

Special warnings and precautions: Poss.worsen.of depress.& emerg.of suic.ideal./ self-harm in bipol.disord., monit.pts.esp.dur.early ther.& dos. chang.for clinic.worsen.& suicidal., risk persist.unt.signif.remiss.occurr, observ.same precaut.as those for other psychiatr.disords., caref.monit.of pts.at great.risk eg. those with suic.relat.events hist./ exhib.suic.ideal.prior to ther.init., metabol.paramet.to be assess. bef.init.treatm.& chang. contr., consid. neutropenia in infect./unexpl.fev. & manage clin. appropri., discont if neutrophil <1,0 x 10⁹/L, monitor for infect. signs/sympt. & neutrophil counts (until >1.5 X 10⁹/L). , weight chang/ weight gain/ lipid chang./ elderly/ pts.with intest.obstruct./ ileus, known CV dis./ other condits.predispos.to hypotens., sleep apnoea, pts. with hist.of alcoh./ drug abuse, pts.at risk for aspirat.pneum., seiz.hist., cons.discont.if tard.dyskin es.S&S occur, discont.if sympt.of neurolept.malign.syndr.occur, QT prolong.family hist., concom.meds.known to incr.QT interv./ concom.neurolept.esp.in pts.with incr.QT prolong.risk, not for use in elderly with dement. exhibit.behav.disturbs., low.effect.dos.in elderly when consid.essent., compar.to placebo elderly pts.with dement.-relat.psychos.at incr.risk of death, elderly with Parkinsons, concom.anticholiner., pts.with curr.diagnos./ hist.of urin.retent./ prostat.hypertrophy/ intestin.obstruct/ incr.intraocul.press./ narr.angle glauc., monit.gluc.contr.of exist.diabet./ hyperglycaem. sympt.in those at risk, fast.bld.gluc.test.advis.for those develop.hyperglycaem. sympt.dur.ther., cont. anti-diab.meds.poss.necess.despite ther.discont., cardiomyopathy/ myocardit., poss.reduc.ment.alertn.& pts.to avoid driv./ operat.machin.unt. suscept.known, ortostat.hypotens.risk, lact.intol., concom.grapefr.juice not recomm., poss.dos.adjustm.with phenytoin/ othr concom. hepat.enzyme induc., concom.anitihypertens.or caus.electrol.imbal., reduce dos.if phenytoin/ carbamaz./hep.enzyme induc.replac.with non-inducer (eg. sodium valproate), ren./ hepat.impairm.

Interactions: Other CNS act.drugs & alcoh.poss.aggrav.prim.CNS effs., incr.clear.with concom.thioridazine/ carbamazepine/ phenytoin/ othr hepat.enzyme induc., signif.incr.in quetiapine AUC with ketoconazole, ser.conc.poss.incr.with grapefr. juice, incr. plasma conc. with concom.P450 3A4 inhibit

QUETIAPINE BIOTECH, Biotech [P/S]

Quetiapine

Indications: Schizophren., manic episod.assoc. with bi-polar disord. for which safety & effic. beyond 12 wks. not demonstrat.

(S5) TABS. 45/2.6.5/0212, 0213, 0214, 0215

721744-001: 25 mg, 100, R271,51

721745-001: 100 mg, 100, R462,85

721746-001: 200 mg, 60, R497,70

721747-001: 300 mg, 60, R581,72

Dosage: Adults: Admin.twice dly.

Schizophren: Tot.dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day. Adjust.dos.within 150-750 mg / day range depend.on clinic.respons. & tolerab.

Bipol.disord.assoc.manic episod: Tot.dly.dos. for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Furth.dos.adjustm. up to 800 mg/day by day 6 in increm.of no great.than 200 mg/day. Adjust dos.accord.to clinic. respon. & tolerab.with range of 200-800 mg/day. Usual effect.dos.: 400-800 mg/day.

Elderly: Init.25 mg/day, theraft.incr.dly.dos.in increm. of 25-50 mg.to an effect.dos.depend.on indiv. respons.& toler.

Contraindications: *Safety in advanc.liv.& ren. impairm./ pregn.& lactat.not est., safety & effic.in childr.& adolesc.und 18 yrs.not est., not indic.for elderly pts.with dement.-relat.psychos., concom. P450 3A4 inhibits., lact.intol.*

Side effects: *Hyperglycaem.sometim.extreme assoc. with ketoacidosis./hyperosmol.coma/death, pass. sev.neutropen., somnol., dizzin., dry mouth, asthen. GI disturbs., dysphag., tachycard., orthostat. hypotens, weight gain, CNS effs., neurolept. malign.syndr., bld.disords., periph.oed., headache, dysarth., anx., extrapyramid.sympt./syndr., hyperton., hypokines., seiz., tard./dyskines., restless leg.syndr., psych.disords., palpitat., asthen., withdr.sympt., pyrex., myalg., hypotherm., jaund., hepatit., rhinit., chest/back/ear pain, dyspn., hypersens.incl.angioed./anaphylax., Stev. Johns. syndr., ven.thromboembol., elev.ser. transamin./ cholester. & triglycer., incr.bld.gluc.to hyperglycaem. lev., sex.dysfunct., priapism, galactorrh., breast swell., menstr.disords., inappropr. antidiuret.horm.secret., hypothyroid., rhabdomyolys., diab.mellit./exacerbat.of pre-exist. diab., hyponatraem., dry eyes, blurr. vis., cataract format., UTI, ac.withdr.sympt.aft.abrupt withdr., suic./ relat.events in pts.< 18 yrs.*

Special precautions: *Monit.gluc.contr.of exist. diabet./ hyperglycaem., pts.develop. hyperglycaem. sympt.dur.ther. to undergo fast.bld. gluc. test, cont.anti-diab.meds.poss.necess. despite ther.discont., benef./risk assessm.in elderly pts.with dement.tak.stroke risk into account, monit.elderly esp.dur.init.dos.per., stroke/ VTE risk fact., discont.ther.if neutroph.count <1,0X 10⁹/t /jaund./neurolept.malign.syndr.sympt./tard. dyskines. S&S devel., tard.dyskines.sympt.poss. arise/ wors.aft.ther.discont., aspirat.pneumon. risk, subst.abuse/seiz.hist., concom.antihipertens. /meds. prolong.QTc interv., poss.dos.adjustm.with phenytoin/other concom.hepat.enzyme induc., reduc. dos.with non-induc.eg.sod.valproate, known CV/ cerebrovasc. dis./condits.predispos.to hypotens., withdr.grad., caref.monit.of high-risk pts. incl.suic./clinic.worsen., QT prolongat.fam. hist./concom.meds.known to incr.QT-interv./concom. neurolept.esp.pts.with incr.risk of QT prolongat., ren./hepat.impairm., lipid chang.*

Drug interactions: *CNS effs.of other CNS depress. incl.alcoh.enhanc., incr.clear.with concom. carbamazepine/phenytoin/thioridazine, act. of dopaminerg.antonag., decr.clear.with cemetidine, decr.lorazepam clear., signific.incr.in quetiapine AUC with ketoconazole.*

QUETZ, (Zydus) Aurobindo [P/S]
Quetiapine.

Indications: *Schizophren., manic episod.assoc. with bipol.disord.for < 12wks*

(S5) TABS. 45/2.6.5/0646, 0647, 0648, 0649

3004143-001: 25 mg; 100; **R225,95**

3004145-001: 100 mg; 90; **R425,95**

3004146-001: 200 mg; 60; **R405,95**

3004147-001: 300 mg; 60; **R509,94**

Dosage: Adults: Admin.twice dly.

Schizophren: Tot.dly.dos.for 1st 4 days: Day 1: 50 mg, day 2: 100 mg, day 3: 200 mg & day 4: 300 mg. Titr.dos.from 4th day to effect.dos.range of 300-450 mg/day. Adjust.dos.within 150-750 mg / day range depend.on clinic.respons. & tolerab.

Bipol.disord.assoc.manic episod: Tot.dly.dos. for 1st 4 days: Day 1: 100 mg, day 2: 200 mg, day 3: 300 mg & day 4: 400 mg. Furth.dos.adjustm. up to 800 mg/day by day 6 in increm.of no great. than 200 mg/day. Adjust dos.accord.to clinic. respon. & tolerab.with range of 200-800 mg/day. Usual effect.dos: 400-800 mg/day.

Elderly: Init.25 mg/day, theraft.incr.dly.dos.in increm. of 25-50 mg.to an effect.dos.depend.on indiv. respons.& toler.

Contraindications: *Safety in pregn.& lactat.not est., safety & effic.in childr.& adolesc.not est., safety in advanc.ren.& liv.impairm.not est., elderly pts. with dement.exhibit.behav.disturbs.*

Side effects: *Freq: Leucopen., dizzin., somnol., syncope, tachycard., asthen., periph.oed., weight gain, elev. in ser.transaminas (ALT, AST). Less freq: Eosinophil., neutropen., hypersens., dose-relat.decr.in thy.hormone lev.incl total T4 & free T4, anorex., seiz., dysarthr., hyperton., extrapyramid. sympts., asymptomat.changes in lens of the eye, abnorm.vis., palpitat., prolongat. of QTc interv., hypotens., orthostat.hypotens., dyspn., pharyngit., rhinit., abdom.pain, incr.sweat., menstr. changes, galactorrh., elev.in gamma-GT lev./non-fast.serum triglyceride, headache, flu-like sympts, fev. Rare: Priapism, neurolept.malign.syndr. Freq.not known: Rise. in prolact.conc., anx., dry eyes, ear pain, hypertens., diarrh., dry mouth, constipat., dyspeps., myalg., UTI, back/chest pain.*

Warnings and special precautions: *Hepat. impairm., safety & effic.in childr.& adolesc.not est., monit.gluc.contr.of exist.diabet./ hyperglycaem. sympt.in those at risk, cont.anti-diab. meds.poss.necess.despite ther.discont., caref. monit.for poss.suicide ideat., risk fact.for leucopen.& /neutropen.incl.pre-exist.low WBC/ drug induc.hist.thereof., pts.to report S&S consist. with agranulocytos./infect., managem.of metabol. paramet.reg.dur.treatm., elderly esp.init.due to orthostat.hypotens.& accid.injury risk, known CV/ cerebrovasc.dis.& other condit.predispos.to hypotens., seiz.hist., consid.dos.reduct./discont.if S&S of tard.dyskines.occur, do not incr.dos.if extrapyramid.sympts.exper., discont.if sympt.of neurolept. malign.syndr.occur, concom.meds. known to prolong QTc interv./fam.hist./risk fact.of QT prolongat., withdr.grad., sleep apnoea risk fact., concom.meds.with anti-cholinerg.effs./urin. retent./signif.prostat.hypertrophy/intestin.obstruct.or relat.condits/incr.IOP/narr.angle glauc., aspirat. pneumon.risk, suspect.cardiomyopathy/myocardit., high.intestin.obstruct.risk & concom.meds.decr. intestin.motil., VTE risk fact., pancreatit.assoc.risk fact., alcoh./drug abuse hist., poss.dos.adjustm. with carbamazepine/phenytoin/other concom. hepat. enzyme induc., monit.weight gain, cont. lact., compar.to placebo elderly pts.with dement.-relat.psychos.at incr.risk of death, elderly with Parkinsons, reproduct.toxic.in anim.stud., caut.on ability to drive/operat.machin.*

Interactions: *Centr.effs.of other CNS depress.& alcoh. enhanc., incr.clear.with concom. thioridazine, decr.plasma conc.with enzyme induc. eg. carbamazepine/phenytoin/barbits./rifampicin, incr. plasma conc.with potent inhibits.of CYP3A4 eg.macrolides & azole antifung.*

REDILANZ, Dr Reddy's [P/S]
Olanzapine.

Indications: *Psychot.disords., ac.episod.of mod.-sev.mania & prev.of recur.manic/depress.episod.of bi-pol.disord.*

(S5) TABS. 42/2.6.5/0814, 0815, 0816

715683-002: 2,5 mg, 28, **R294,85**

715684-002: 5 mg, 28, **R456,25**

715685-002: 10 mg, 28, **R593,25**

Dosage: **Psychot.disords:** Admin.as once-a-day dos. Init: 5-10 mg/day with target dos.of 10 mg/ day within several days. If indic. dos.adjustm. should occur at interv.of not less than 1 wk. Dos. range: 5-20 mg/day. Only incr.dos above recomm. 10 mg/day aft.clinic.assessm. Cont.respond.pts.at low dos. to maint.remiss.& assess periodic.

Ac.man.& bipol.disord: Init.10 mg/day. Dos. adjustm. if indicat.within range of 5-20 mg/day at interv.of not less than 24 hrs.

Prev.recurr.in bi-pol.disord: Recomm.start. 10 mg/day. Pts.already reciv.Redilanz should cont.at same dos.to prev.recurr. Incr.dos.to great.than recomm.start.dos. within range of 5-20 mg dly only aft.clinc.assessm. & at interv.of not less than 24 hrs.

Safety of dos.above 20 mg/day not eval.

Contraindications: *Known narrow-angl. glauc. risk, safety in pregn.& lactat.& childr.und 18 yrs. not est., dement. relat.psychos.behav.disords.in the elderly.*

Side effects: *Freq: Eosinophil., weight gain, incr.appet., hyperglycaem., hypertriglyceridaem., personality disord., somnol., dizzin., headache, akathis., parkinson., dyskines., asthen., agit., movem.disord., abnorm.gait, trem., imp.articulat., hyperton., amblyop., chest pain, orthostat. hypotens., hypotens., periph.oed., rhinit., pneumon, dry mouth, constipat., trans. asymptomat. hepat.transamin.elev., photosens. reacts., elev. prolact.lev. Less freq: Allerg.reacts., amnes., anx., euphor., hostil., nervoun., myoclon., insomn., stutter., extrapyramid.effs., seiz., NMS, dyston., tard.dyskines., speech disords., bradycard., tachycard., ECG paramet.changes, ventric. tachydysrhythm., cough, pharyngit., abdom.pain, pancreatit., hepatit., rash, extrem. pain, joint pain, rhabdomyolys., premenstr.syndr., priap., fev., intent.injury, high creatine phosphokin. Freq. unknown: Leucopen., thrombocytopen., neutropen., diab.developm./-exacerbat., diabet. ketoacidosis, diabet.coma, blepharit., corn.les., ven.thromboembol., resp.infects., back pain, urin. incontin., decr.erythrocyt.count./haematocrit/ Hb/ leucocyte count/lymphocyte./thrombocyte.& platel., incr.MCHC/lymphocyte./monocyt.& eosinophil., decr.bicarbon./Ca phosphor./album & tot.prot., incr.Cl/GGT & phosphor.*

Special warnings and precautions: *Elev. prolact. lev.persist. modestly dur.chron.admin.with incr.in mammary gland neoplasms in rodents thought to be prolactin mediat., discont.if any clinic.NMS manifestat./high fev.observ., consid. discont./dos.reduct.if tard. dyskines. S&S develop, tard.dyskines.risk incr.with long-term expos., cholinerg.syndr.on discontin., monit.exist.diab.for worsen.gluc.contr., monit. pts.start.treatm.at risk of diab.for hyperglycaem., fast.bld.gluc.if hyperglycaem. develops, some pts.req. continuat. of anti-diabet. treatm.despite discont., hist.of seiz./condits.assoc.with seiz./low.seiz.thresh., symptomat.prostat.enlargem., narr.angle glauc., paralyt.ileus & relat.condits., card.pts./ condits. predispos.to hypotens.due to orthostat. hypotens. risk, S&S of hepat.impairm., pre-exist. condits. assoc. with limit.hepat.funct.reserve, concom. potent.hepatotox.meds., predispos.risk fact.in elderly, card.vasc.adverse events incl.stroke in elderly dement.pts., leucopen./neutropen., meds. induc.bone marrow depress./toxic., bone marrow depress., hyper eosinophil.condits., myeloproliferat. dis., plasma clear.high.in smokers, concom.centr. act. gents & alcoh., concom.fluoxetine not recomm., concom.meds.known to incr.QTc interv./ congenit. long QT syndr./CHF/card.hypertrophy/ hypokalaem. & hypomagnesaem., discont.if hepatit. diagnos., grad.discont.*

Interactions: *Fluoxetine incr.conc.& decr. clear., may antagon.effs.of levodopa & dopamine agonists, may enhanc.effs.of cert.antihipertens., reduc.bioavail.with activat.charc., metabol.poss. induc.by smok.& carbamazepine, CYP1A2 inhibit. reduc.clear., CYP1A2 induc.incr.clear., valproate has little eff.on metabol.*

REXULTI, Lundbeck [P/S]
Brexipiprazole

Indications: *Schizophren.in adults*

(S5) TABS. 51/2.6.5/0501, 0502, 0503, 0504, 0505

3002989-001: 0,5mg; 28; **R768,31**

3003028-001: 1mg; 28; [R768,31](#)
3003029-001: 2mg; 28; [R1 024,40](#)
3003031-001: 3mg; 28; [R1 480,06](#)
3003033-001: 4mg; 28; [R1 480,06](#)

Dosage: Schizophren: Recomm.start.dos.1 mg once dly on days 1 - 4. Titrate to 2 mg once dly.on day 5 - day 7 & to 4 mg on day 8 bas.on clinic. respon. & tolerabil. Target dos.range & maint. dos: 2-4 mg once dly. Max.dly.dos: 4 mg. Reass. periodic.to determ.contin.need for maint.treatm.

Hepat.impairm. & mod./ sev./ end-stage ren.impairm: Max.recomm.dos.: 3 mg once dly.

Dos.modificats: Known CYP2D6 poor metabolisers: Half usual Rexulti dos.; known CYP2D6 poor metabolisers tak.strong/mod.CYP3A4 inhibit.: Quarter usual Rexulti dos.; with concom. strong CYP2D6 inhibits.&/strong CYP3A4 inhibits: Half usual Rexulti dos.; with concom.strong/mod. CYP2D6 inhibits. & strong/mod. CYP3A4 inhibits: Quarter usual Rexulti dos.;with concom.strong CYP3A4 induc: Double Rexulti dos.over 1-2 wks. Rexulti dos.to be reduc.to origin.lev.when concom. CYP3A4 induc.is withdr.

Contraindications: *Safety & effic.in pts.und.18 yrs./ pregn.& lactat.not est., dement.-relat. psychos.*

Side effects: *Common: Diarrh., naus., weight incr., bld.creatine phosphokin.incr., back pain, akathis., dizzin., trem., extrapyramid.sympts., incr. fast.gluc./fast.lipids., HDL decr. Less common: Upper abdom.pain, dent.caries, flatul., pain/pain in extremit., incr.BP, bld triglycerid.incr., myalg., sedat., cough, rash. Unknown: NMS, suicid. thoughts/ behav., cerebrovasc.adv.reacts., tard. dyskines., impulse-contr.disords., orthostat. hypotens., syncope, falls, seiz., body temp. dysregulat., dysphag.*

Warnings and special precautions: *Incr. mortal. report. in elderly with dement.-relat. psychos., known CV/cerebrovasc.dis., monit.high risk pts.for suic., discount.all antipsychot.meds.if S&S of neurolept. malign.syndr.develop/unexpl. high fev. without addit.clin.manifestats.of NMS, reconsid. dos. reduct./discount.if sympts.of tard.dyskines. devel., monit.diab.mellit./high risk pts.for worsen.control & do fast.bld.gluc.for pts.develop. hyperglycaem.sympts., clin.monit.of weight recomm., freq CBC monit.dur.first mnths.of treatm.in pts with pre-exist.low WBC/ANC or hist. of drug-induc.leucopen./neutropen., monit.pts with neutropen.for fev./S&S of infect., discount.in sev. neutropen., concom.meds.known to prolong QT interv./ family hist.of QT prolongat./electrol. imbal. / known.CV dis., identify VTE risk facts.bef./dur. ther.& prevent.meas.taken., condits.predispos.to hypotens., pts.at risk of fall, seiz.disord.hist./ condits. lower.seiz.thresh., condits contrib.to elev. core body temp.incl.exercer./heart expos./concom. anticholinergs./ dehydrat., oesophag.dysmotil.& aspirat. assoc.with antipsychot.drug use theref. core in aspirat.pneum.risk pts., monit.for developm. of new/ hist. of impulse-contr. disords. & consid dos.reduct./discount.treatm if pt.dev.such urges, hepat./ren.impairm., not est.in pts.> 65 yrs., lact.intol., pts.receiv. strong CYP2D6 &/CYP3A4 inhibits./strong CYP3A4 induc., monit.pt.clos.as clinic.improvem.may take sev.days to wks., effect. contracept.in women of childbear.potent., decr. female fertil.in animal studies.*

Interactions: *AUC incr.by quinidine & other potent CYP2D6 inhibits., AUC incr.by ketoconazole/ other potent CYP3A4 inhibits, decr.AUC & C_{max} with rifampicin/other potent CYP3A4 induc.*

RISNIA, Cipla Medpro [P/S]

Risperidone

Indications: *Ac. & chron.schizophren.psychos. & relat.psychos.where posit.&/or negat.sympts.are promin., affect.sympts.assoc.with schizophren., maint.clinic. improvem. where init.treatm.reponse shown, mania in pts.with bipolar disord.incl. disrupt. & aggress.behav., conduct & disrupt. behav. disords.in childr. 5-12 yrs.with bel.aveg. intellect. funct./ment.retard.where destruct. behav. is promin.*

(S5) TABS, 42/2.6.5/0792, 0793, 0794, 0795

717996-001: 0,5 mg, 30, [R120,90](#)

717997-001: 1 mg, 30, [R223,50](#)

717998-001: 2 mg, 30, [R477,00](#)

717999-001: 3 mg, 30, [R642,30](#)

Dosage: Schizophren: When switch.from other antipsychot. & if medic.appropr.discont.prev. treatm.grad. If switch from depot antipsychot.init. Risnia in place of next sched.inj. Re-eval.cont. exist. anti-Parkinson meds.period.

Adults: Admin.1-2xdlly. Init.2 mg/day.incr.to 4 mg on 2nd day, indiv.furth.if reqd. Usual optim.dos.is 4-8 mg/ day. Dos.above 6 mg/day when admin. twice dly.assoc.with more extrapyramid. sympts. & other adverse effs. & gen.not recomm. Slow titrat.phase & low.start./maint.dos.may be approp. in some pts.esp.with first ac.psychos. episod. Dos.above 10 mg/day not shown to be superior in effic. & may incr.incid.of S/E & only consid. aft.eval.risk vs.benef. Max.tot.dly.dos: 16 mg/day. Add benzodiazep.if addit.sedat.reqd.

Elderly: Init.0,5 mg 2x dly.adjust.indiv.in 0,5 mg 2xdly.increm.to 1-2 mg 2x dly.

Bipol.mania: Admin.once dly start.with 2 or 3 mg/day. Dos.adjustm.if indic.at interv.of not short.than 24 hrs & in increm.of 1 mg/day. Effic.shown in dos range of 1-6 mg/day. Eval.& justif. cont. treatm.on ongoing basis.

Conduct & disrupt.behav.disords.in childr. 5-12 yrs: <50 kg: Init.0,01 mg/kg once dly.recomm. Indiv. adjust.in increm.of 0,01 mg/kg once dly.not more freq. than every other day if need. Recomm. maint.dos: 0,02-0,04 mg/kg once dly. Mean aveg. dos: 0,03 mg/kg once dly. Eval.& justif.on ongoing basis. Oral sol.advis.for childr requir.less than 0,5 mg/dos.or unable to swall.tabs.

Contraindications: *Safety & effic.in childr.und. 5 yrs.for conduct & other disrupt.behav.disords. not est., Parkinson's dis.& Lewy body dement., safety in pregn.& lactat.not est., safety & effic.in childr.und. 15 yrs.for schizophren.not est., limit. exper.in bipol.mania in childr.& adolesc.young. than 18 yrs.*

Side effects: *U/LRTI, eye/vir.infects., flu, UTI, cellulit., acarodermatit., onychomycos., cystit., gastro-enterit., infect., bld.dyscras., anaphylact./ allerg. reacts., hypersens., incr.plasma prolact.lev., body temp. dysregulat., water intox.due to polydips./ SIADH, diab.mellit.aggravat., ketoacidosis, hyperglycaem., diab.coma, appet. chang., psych. disords.incl.mania/hypoman., CNS effs. incl.parkinsonism, dizzin., headache, extrapyramid. sympts.incl.trem.bradykines./ dyskines./ oculogyr.cris., akathis., ac.dyston., tard. dyskines., CVA incl.stroke/TIA, neurolept. malign. syndr., convuls., syncope, hypo-/paraesthes., tard. dyston., Parkinson's dis. aggrav./deterior., bal./ movem.disord., involunt. musc.contract., mask. facies, cerebr.ischaem., blurr.vis., conjunctivit., eye disords.incl.ocul.hyperaem./glauco./retin.art. oclus., vertigo, ear/chest/back/neck/ musculoskelet./ buttock pain, tinnit., card.disords. incl. AV block/tachycard./atrial fibrillat./prolong. QT interv., orthostat.hypotens., hypertens., flush., nas./ resp./pulm.congest., cough, dyspn., pulm. embol., epistax., wheez., dysphon., rales, hypervent., nas.oed., toothache, decr.salivat., anorex., intest.obstruct., pancreatit., dysphag., faecaloma, cheilit., aptyalism, jaund., skin reacts. incl.incr.pigment., seborrh.dermatit., alopec., arthralg., musc.weakn., joint swell./stiffn., rhabdomyolis., torticoll., urin./faec.incontin., micturit./ menstr./sex.funct.disturbs., polyur., enures., dysur., pollakur., galactorrh., breast/chest discomf., erect./ejaculat./orgasm.dysfunct., priapism, gynaecomast., pyrex., periph.oed./ coldn., asthen., fatig., malaise, thirst, chills, hypo-/hypertherm., ECG abnorm., incr.bld.gluc./ prolact./ hepat.enzym., weight chang., fall, hyperglycaem. somet.assoc.with ketoacidosis/ hyperosmol. coma/death, benign pituat.adenoma.*

Special precautions: *Excret.in breast milk, advdrs. eff.observ.in neonat.expos.dur.last trimest. of pregn., ren./liv.impairm., tard.dyskines., elderly, epilep., concom.furosemed./alcoh./other centr. act. meds., avoid dehydrat., excess.eat.as poss. weight gain, pre-exist. diab.mellit.exacerb., incr. CV events/mortalit.risk in elderly pts.with dement., fast.bld.gluc.test advis.if hyperglycaem. devel., monit.hyperglycaem. sympt.in pts.with diab. mellit.risk fact., tard.dyskines.risk fact., cons. benef./ risk in Parkinson dis. as risk pts.devel.NMS & incr. antipsychot. meds.sens., known CV dis. where grad. dos.titrat.recomm., consid.dos. reduct. if hypotens.occurs, concom.meds.known to prolong. QT interv., Parkinson.S/E developm.poss. predict. of TD & TD risk poss.incr.with treatm. durat. & tot. antipsychot. cumulat.dos., treatm.may suppress. S&S of TD mask.underly.process., reg. assessm. for contin.ther., consid.ther.discont.if TD S&S appear, discount.all anti-psychot./non-essent. meds. in NMS.sympt./treatm.& monit., consid.re-introd. caref.& monit.aft.NMS recov.as NMS recurr. report., prevent.hypo-oestrog.bone loss ther. in premenopaus.women with second. amenorrh. of >6mnths., lact.intol.*

Drug interactions: *Use with other concom. meds. not system.eval., may antagon.eff.of levodopa & other dopamine agonists, carbamazepine & other hepat.enzyme induc.may decr. plasma lev., valproate T_{max}incr., incr.plasma lev. with phenothiaz./TCA's/some β-block./ fluoxetine. & paroxet., venlafaxine decr.clear., cimetidine & ranitidine incr.bioavailabil., Li-T_{max} incr., poss.torsades de pointes with meds.prolong. QT interv.*

RISPACOR, Accord [P/S]

Risperidone

Indications: *Ac. & chron.schizophren.psychos. & relat. psychos.where posit.&/or negat.sympts.are promin., affect.sympts.assoc.with schizophren. alleviat., maint.clinic.improvem.where init.treatm. response shown, behav.disturbs.in pts.with dement. when aggressiven./activ.disturbs./psychot.sympts. are promin., conduct & disrupt.behav.disords.in childr. 5-12 yrs.with subaveg.intellect.funct./ment. retard. where destruct. behav.is promin.*

(S5) TABS, 42/2.6.5/0155, 0156, 0157, 0158

714101-001: 0,5 mg, 30, [R120,90](#)

713967-001: 1 mg, 30, [R223,50](#)

713966-001: 2 mg, 30, [R477,00](#)

713965-001: 3 mg, 30, [R642,30](#)

Dosage: Schizophren: When switch.from other antipsychot. & if medic.appropr.discont.prev. treatm.grad. & if switch.from depot antipsychot. init. Rispacor in place of next sched. inj. Re-eval. cont.exist. anti-Parkinson meds.period. **Adults:** Admin. 1-2xdlly. Init.2 mg/day. May be incr.to 4 mg on 2nd day, indiv.furth.if reqd. Usual optim.dos: 4-8 mg/day. Dos.above 6 mg/day when admin.twice dly. assoc.with more extrapyramid.sympts.& other adverse effs.& gen.not recomm. Slow.titr.phase & low. start./maint.dos.may be approp.in some pts. esp.with first ac.psychot.episod.

Dos.above 10 mg/day not shown to be superior in effic. & may incr.incid.of S/E & only consid.aft. eval. risk vs.benef. Max.tot.dly.dos: 16 mg/day. Add benzodiazep.if addit.sedat.reqd. **Elderly:** Init. 0,5 mg 2x dly.adjust.in 0,5 mg 2xdly.increm.to 1-2 mg 2x dly.

Behav.disturbs.in adult dement.pts: Init. 0,25 mg 2xdly. Indiv.if necess.in increm. of 0,25 mg 2xdly.not more freq.than every other day if need. Optim. dos: 0,5 mg 2xdly.with some benefit.from dos. of upto 1 mg 2xdly. Once target.dos. reach. consid. once dly.dos. Eval.cont.treatm.regul.

Conduct & disrupt.behav.disords.in childr. 5-12 yrs: <50 kg: Init: 0,01 mg/kg once dly. Indiv. adjust. in increm.of 0,01 mg/kg once dly.not more freq.than every other day. Recomm.maint.dos: 0,02-0,04 mg/kg once dly. Mean dos: 0,03 mg/kg once dly. Eval. ongo.need regul.

Contraindications: *Safety & effic.in childr.und. 5 yrs.for conduct & other disrupt.behav.disords.not est., Lewy antibody dement.*

Side effects: Tard.dyskines.most.in elderly & esp. elderly fem., neurolept.malign.syndr., hyperglycaem. assoc.with ketoacidos./hyperosmol. coma/ death, CVA & TIA's, orthostat.hypotens., seiz., weight gain, headache, fatig., angioed., allerg. reacts., decr.neutroph.&/thrombocyte count, rhinit., water intoxicat.due to polydips./SIADH & body temp.disregulat., incr.plasma prolact.lev.& assoc.manifestat., psych.disords., somnol., CNS effs., dizzin., dos.depend.extrapryamid. sympts.incl.trem./rigidit./oculogyrr.cris./akathis./ac.dyston./hypokines., blurr.vis., refl.tachycard., hypo-/hypertens., GI disturbs., skin reacts., urin.incont., erect.-/ejaculat./orgasm.dysfunct., priapism, gynaecomast./galactorrh./menstr.cycle disturbs.& amenorrh., hyperglycaem./diab.mellit. exacerbat.

Special precautions: High.mortality.report.in elderly.dement.pts.receive.furosemide, avoid dehydrat. with concom.furosemide, diab.mellit./risk fact., fast.bld.gluc.test.advis.in pts.develop.hyperglycaem.sympt., Parkinson.dis./dement.with Lewy bodies is at risk of NMS.& incr.antipsychot.meds.sensitiv., concom.alcohol.& other central.act.meds., known CV dis.where grad.dos.titrat.recomm., consid.dos.reduct.if hypotens.occurs, epilep., safety.in pregn.& lactat.not est., excret.in breast milk, re-eval.ther if concom.fluoxetine/ paroxetine init./discont., safety & effic.in childr. und.15 yrs.for schizophren.not est., ren.& liv. impairm., treatm.may suppress.S&S of TD poss. mask. underly.process., prescrib.in manner to minim. TD risk, reg.assess.contin.ther., discont.ther. if S&S of tard.dyskines., discont.all anti-psychot. & not essent.meds.if NMS devel., consid. re-introduct.caref.& monit.aft. NMS recov.as NMS recurr. report., dos.-depend.plasma prolact.conc. poss. occur, preventat.hypo-oestrog.bone loss ther. in premenopaus.women with second.amenorrh.of >6 mnths., warn pts.of poss.weight gain, no caus. Assoc0. detect.with report benign pituit.adenomas., not for lact.intol.indiv., elderly, high incid.CVA & TIA in elderly with dement., limit.exper.in childr. und. 5 yrs.

Interactions: Carbamazepine /other hepat. enzyme induc.may decr.plasma lev., valproate/Li T_{max} incr., slight decr.bioavail with topiramate, incr. plasma lev.with phenothiaz./TCA's/some β -block./ fluoxetine & paroxet., incr.AUC /decr.clear.with venlafaxine, cimetidine & ranitidine incr. bioavailabil.

RISPERLET, (Sanofi Aventis) Janssen-Cilag [P/S]

Risperidone

Indications: Ac.& chron.schizophren.psychos.& relat. psychos.where posit.&/or negat.sympts. are promin., behav.disturbs.in pts.with dement. when aggressiven./activ.disturbs./psychot. sympts. are promin., conduct & disrupt.behav. disords.in childr. 5-12 yrs.with subaveg.intellect.funct./ ment. retard.where destruct.behav.is promin.

(S5) TABS, A40/2.6.5/0727, 0728, 0729

711419-001: 0,5 mg, 30, [R304,54](#)

711420-001: 1 mg, 30, [R526,14](#)

711421-001: 2 mg, 30, [R886,01](#)

Dosage: Schizophren: When switch.from other antipsychot. & if medic.appropriate discont.prev. treatm.grad.& if switch.from depot antipsychot. init. Risperlet in place of next inj. Re-eval.need for cont.exist.anti-Parkinson meds. period. Dos. above 10 mg/day have not been shown to be superior in effic.& may incr. incid.of S/E & should only be consid.aft. eval.risk vs. benef. Add benzodiazep. if addit. sedat.reqd.

Adults: Indiv. Admin.1-2xdly. Init. 2 mg/ day.incr. to 4 mg on 2nd day, indiv.furth.if reqd. Usual optim. dos.is 4-8 mg/day. Max.tot.dly.dos: 16 mg/ day. Elderly: Init.0,5 mg 2x dly.adjust. in 0,5 mg 2xdly. increm.to 1-2 mg 2x dly.

Behav.disturbs.in pts.with dement: Init. 0,25 mg 2xdly. Indiv.if necess.in increm.of 0,25 mg 2xdly.not more freq.than every other day. Optim. dos: 0,5 mg 2xdly.with some benefit. from dos.of upto 1 mg 2xdly. Once target.dos. reach.cons. once dly. dos. Eval.cont. treatm. reg.

Conduct & disrupt.behav.disords.in childr.5-12 yrs: <50 kg: Init.0,01 mg/kg once dly. Indiv. adjust. in increm.of 0,01 mg/kg once dly.every other day. Recom.maint.dos: 0,02-0,04 mg/kg once dly. Mean dos: 0,03 mg/kg once dly. Eval. ongoing need reg.

Contra-indications: Safety & effic.in childr.und. 5 yrs.for conduct & other disrupt.behav.disords. not est., Lewy body dement., pregn.& lactat., safety & effic.in childr.und.15 yrs.for schizophren. not est., galactose intol./lapp lactose defic or gluc.-galact.malabsopt.as contains lactose

Side-effects: Tard.dyskines.most.in elderly & esp. elderly fem., neurolept.malign.syndr., hyperglycaem.assoc.with ketoacidos.& coma/ death, cerebrovasc.accid.& TIA's, orthostat.hypotens., seiz., headache, weight gain, fatig., angio-oed./skin rash & other allerg.reacts., decr. neutropil &/thrombocyte count, hyperprolactinaem., inappropri.antiidiuret. hormone secret., galactorrh./gynaecomast./menstr. cycle disturbs.& amenorrh., dos.depend. extrapyramid.sympts.incl.trem./rigidity/ hypersalivat./bradykines./oculogyrr.cris./akathisia/ ac.dyston.& hypokines., CNS effs., blurr.vis., tachycard., hypertens., GI disturbs., polydips., water intoxicat., psych.disords., erect.-/ejaculat./orgast.dysfunct., priapism, rhinit., urin.incont., body temp.disregulat., imp.ment. alertn.

Special precautions: High.mortality.report.in elderly.dement.pts.receive.furosemide, avoid dehydrat.in pts.receive.furosemide, monit.gluc. control in diab.mellit., diab.mellit.risk fact., Parkinson.dis., sometimes diffic.to differen. advers. effs.from sympts.of underly.psychos., concom.alcohol.& other central.act.meds., known CV dis. where grad.dos.titrat.recomm., consid. dos. reduct.if hypotens.develops, epilep., excret.in human breast milk, ren.& liv.impairm., prescrib. in manner to minim.TD risk, reg.assess contin.ther., with S&S of tard.dyskines.cons. discont., discont.all anti-psychot.& not essent. meds. if neurolept.malign.syndr.develops, consid. re-introduct. caref.& monit. aft.NMS recov.as NMS recurr.report., preventat.hypo-oestrog. bone loss ther.in premenopaus.women with second. amenorrh.of >6mnths., no caus.assoc.detect. with report benign pituit.adenomas.

Drug interactions: Use with other concom. meds.not system.eval., may antagon.eff.of levodopa & other dopamine agonists, carbamazepine & other hepat.enzyme induc.may decr.plasma lev., incr. plasma lev.with phenothiaz. / TCA's/some β -block./fluoxetine & paroxet., cimetidine & ranitidine incr.bioavailabil.

RISPEVON, (Activo) Trinity [P/S]

Risperidone

Indications: Ac.& chron.schizophren.psychos.& relat. psychos.where posit.&/or negat.sympts. are promin., affect.sympts.assoc.with schizophren., maint. clinic. improvem.where init.treatm.reponse shown, behav.disturbs.in pts.with dement.when aggressiven./ activ.disturbs./psychot.sympts. are promin., conduct & disrupt.behav.disords.in childr. 5-12 yrs.with subaveg.intellect.funct./ment. retard. where destruct.behav.is promin.

(S5) TABS, 43/2.6.5/0039, 0040, 0041, 0042

718226-002: 1 mg, 30, [R218,50](#)

718226-001: 1 mg, 60, [R437,00](#)

718227-002: 2 mg, 30, [R472,01](#)

718227-001: 2 mg, 60, [R944,01](#)

718228-002: 3 mg, 30, [R740,10](#)

718228-001: 3 mg, 60, [R1 480,20](#)

718229-001: 4 mg, 60, [R1 889,62](#)

Dosage: Schizophren: When switch.from other antipsychot. & if medic.appropriate discont.prev. treatm.grad.& if switch.from depot antipsychot. init. Rispevon in place of next sched.inj. Re-eval. need for cont.exist.anti-Parkinson meds.period. Dos.above 6 mg/day when admin.twice dly. are assoc.with more extra pyramid.sympts and other adv. effs.theref.gen.not recomm.

Dos.above 10 mg/day have not been shown to be superior in effic.& may incr.incid.of S/E & should only be consid.aft.eval.risk vs.benef. Add benzodiazep. if addit.sedat.reqd.

Adults: Indiv. Admin.1-2xdly. Init.2 mg/day.incr. to 4 mg on 2nd day, indiv.furth.if reqd. Usual optim. dos.is 4-8 mg/day. Max.tot.dly.dos: 16 mg/day. Elderly: Init.0,5 mg 2x dly.adjust.in 0,5 mg 2xdly. increm.to 1-2 mg 2x dly.

Behav.disturbs.in pts.with dement: Init. 0,25 mg 2xdly. Indiv.if necess.in increm.of 0,25 mg 2xdly.not more freq.than every other day. Optim. dos: 0,5 mg 2xdly.with some benefit.from dos.of up to 1 mg 2xdly. Once target.dos. reach.cons. once dly.dos. Ongoing eval.& justificat. of cont. treatm.

Conduct & disrupt.behav.disords.in childr.5-12 yrs: <50 kg: Init.0,01 mg/kg once dly. Indiv. adjust. in increm.of 0,01 mg/kg once dly.every other day if reqd. Recom.maint.dos: 0,02-0,04 mg /kg once dly. Mean dos: 0,03 mg/kg once dly. Ongoing eval.& justificat.of cont.treatm.

Contraindications: Safety & effic.in childr.und.5 yrs. for conduct & other disrupt.behav.disords.not est., Lewy body dement., safety.in pregn.& lactat. not est., safety & effic.in childr.und.15 yrs.for schizophren. not est., galact.lintol., lapp lactose defic., gluc.-galact.malabsorpt.

Side effects: Tard.dyskines.most.in elderly & esp. elderly fem., neurolept.malign.syndr., hyperglycaem. assoc.with ketoacidos.& coma/ death, cerebrovasc.accid.& TIA's, orthostat.hypotens., seiz., decr.neutrophil & thrombocyte count, water intoxicat.from polydips.or inappropri. antiidiuret. hormone secret., body temp. disregulat., incr.plasma prolact.lev.& manifestat., diabet. mellit./diabet.keto-acidos.aggravat., psych. disords., somnol., imp.conc., CNS effs., dos. depend. extrapyramid.sympts.incl.trem./rigidity/ hypersalivat./bradykines./oculogyrr.cris./akathisia/ ac.dyston.& hypokines., CVA, blurr. vis., tachycard., hypertens., chest pain, dyspn., cough, dry mouth, pharyngit., rhinit., sinusit., URTI, GI disturbs., skin rash, urin.incont., polyur., erect.-/ejaculat./orgasm.dysfunct., priapism, decr.libido, gynaecomast., galactorrh., menstr.cycle disturbs.& amenorrh., headache, weight gain, fatig., angio-oed. & other allerg.reacts., imp.ment.alertn., back pain, arthralg.

Warnings and special precautions: Intraoperat. floppy iris syndr.poss.dur.cataract surg. in pts.treat.with alpha.-adrenerg.antagon. eff. theref.advise surgeon prior to surg., high. mortalit. report.in elderly.dement.pts.receive. concom.furosemide, avoid dehydrat.in pts. receive.furosemide, monit.gluc.control in diab. mellit., diab.mellit.risk fact., high.incid. cerebrovasc. accid.& TIA's report.in elderly with dement., Parkinson.dis/dement.with Lewy bod.at risk of NMS & incr.antipsychot.med.sensitiv., high. mortalit. report.in elderly, concom.alcohol.& other central. act.meds., known CV dis.where grad.dos. titrat. recomm., consid.dos.reduct.if hypotens. develops, epilep., post-market.advers.effs.observ. in neonates expos.dur.last trimest.of pregn., excret. in human breast milk, ren.& liv.impairm., sometimes diffic.to differen.advers.effs.from sympts. of underly.psychos., TD risk incr.with ther. durat.& tot.cumulat.dos., prescrib.in manner to minim. TD risk, reserve treatm.for pts. obtain. substant. benef., reg.assess contin.ther., with S&S of tard.dyskines.cons. discont., discont.all anti-psychot. & not essent.meds.if neurolept. malign. syndr. develops & instit.treatm., consid. re-introduc. caref.& monit.aft.NMS recov.as NMS recurr. report., preventat.hypo-oestrog.bone loss ther. in premenopaus.women with second. amenorrh.of >6mnths., refrain from excess.eat., no caus.assoc.detect.with report benign pituit. adenomas., concom.meds.know to prolong QT interval., re-eval.dos.on discont.of carbamazepine & other hepat.enzyme induc.

Interactions: Use with other concom.meds.not system.eval., may antagon.eff.of levodopa & other dopamine agonists, clin.signif.hypotens.with concom. antihypertens., carbamazepine & other hepat. enzyme induc.may decr.plasma lev., incr. plasma lev.with phenothiaz./TCAs/some β -block./ fluoxetine & paroxet./chron.clozapine, cimetidine & ranitidine incr.bioavailabil., T_{max} of valproate/Li. incr., incr AUC & decr.clear.with concom. venlafaxine

Interactions: *Reduc.bioavail.with activat.charc., CNS eff.enhanc.of other CNS depress.& alcoh., may antagon.effs.of levodopa & dopamine agon., may enhanc.effs.of cert.anti hypertens., QTc prolongat. risk with meds.known to cause QTc prolongat., CYP1A2 inhibit.incl.fluvoxamine decr. clear., CYP1A2 induc.incr.clear., fluoxetine inc. conc. & decr.clear., smok./carbamazepine/omeprazole & rifampicin.low.plasma lev.*

ZYPREXA, Eli Lilly [P/S]

Olanzapine.

Indications: *Psychot.disorders., ac.mod.to sev. mania, prev.recurr.of manic/depress.episod.of bipol.disord.*

(S5) TABS, 32/2.6.5/0685, 31/2.6.5/0058, 0060.

864188-005: 2.5 mg, 28, [R488,81](#)

827509-006: 5 mg, 28, [R720,78](#)

827517-009: 10 mg, 28, [R924,09](#)

(S5) VELOTABS, 38/2.6.5/0030, 0073

707938-001: 5 mg, 28, [R720,65](#)

707939-001: 10 mg, 28, [R924,09](#)

Dosage: Admin.as once-a-day dos. Safety of dos.above 20 mg/day not eval. Velotabs are bioequiv.to coat.tabs. Place Velotabs in mouth immed.aft.open.blister where it will rapid dissolv. in saliva or dispers.in full glass of water/bever. immed.bef.admin.

Psychot.disorders: Init. 5-10 mg/day with target dos.of 10 mg/day within several days. If indic.dos.adjustm.should occur at interv.of not less than 1 wk. Dos.range: 5-20 mg/day. Incr.above routine 10 mg/day advis.only aft.clinic.assessm.

Ac.man.in bipol.disord: Init.dos:10 mg once dly. Dos.adjustm.within range of 5-20 mg/day to occur at interv.of not less than 24 hrs.if indicat.

Prev.recurr.in bipol.disord: Recomm.init.dos: 10 mg/ day. For those receiv.Zyprexa treatm.for manic episod.cont.ther.at same dos. Incr.dos.to great.than recomm.start.dos.within range of 5-20 mg/day only aft.clinic.assessm.at interv.of not less than 24 hrs.

(S5) IM INJ, 35/2.6.5/0307

Indications: *Agitat.&disturb.behav.in schizophren. & relat.psychos., ac.mania assoc. with bipol.I disord.when oral ther.not appropriate.*

702949-001: 10 mg, sngl.vials, [R210,59](#)

Dosage: Tfd.to oral ther.as soon as clinic.indicat. IM use only.

10 mg as sngl.IM inj. May be rep.2 hrs.aft.1st dos.& again 4 hrs.aft.2nd dos.if necess. Dly.dos.exceed. 30 mg not eval.

Contraindications: *Safety in pregn.& lactat.& childr. und.18 yrs.not est., known narrow-angl. glauc. risk, concom.fluoxetine/parenter. benzodiazep. not recomm.*

Side effects: *Asthen., bradycard.(ser./sev.with IM use with apnoea & ventric.tachydysrhythm.), neurolept.malign.syndr., orthostat.hypotens., tachycard., hypotens., GI disturbs., weight gain, hyperglycaem.incl.diabet.coma & ketoacidosis, exacerbat. prev-exist.diab., hypertriglyceridaem., periph.& low. extremity oed., CNS effs.incl.seiz., incr.tard.dyskines.risk with long-term treatm., rash, photosens.react., priapism, bld.dyscras., hepatit., allerg.reacts., ven.thromboembol., rhabdomyolys., eosinophil., incr.incid.of abnorm. gait/falls/urin. incont.in./pneumon./ death/CVA's incl.stroke in elderly with dement.relat.psychos., hallucinat.& Parkinsonian symptomatology in drug induc. psychos. assoc.with Parkinsons*

Special precautions: *Contin.respond.pts.on low. dos.to maint.remiss., elev.prolact.lev.persist. modestly dur.chron.admin., incr.mammary gland neoplasms consid.prolact.mediat.report.in rodents on chron.antipsychot.medicat., concom.cent.r.act. agents & alcoh., discont.if S&S of neurolept. malign. syndr./high fev.observ., hist.of seiz./ condits. assoc.with seiz./low.seiz.thresh., hepat. impairm./concom.potent.hepatotox.meds., monit. exist.diab.for worsen.gluc.contr., monit.pts.start. treatm.at risk of diab.for hyperglycaem., fast.bld. gluc.if hyperglycaem.develops,some pts.req. continuat.of anti-diabet.treatm.despite discont.of suspect.drug, concom.meds.known to incr.QTc interv./ congenit.long QT syndr./CHF/heart hypertrophy/ hypokalaem.& hypomagnesaem., concom. BP low.meds.other than alpha-1 adrenerg. antagon., subst.induc./inhibit.CYP1A2 isoenzyme may affect olanzapine pharmacokinet., poss.reduc. dos. with concom.CYP1A2 inhibit., plasma clear.in smokers higher, card.pts.due to orthostat. hypotens. risk (esp.IM admin.), sympt.prostat. enlargem., narr.angle glauc., paralyt.ileus & relat. condits., recent MI hist./unstable card.dis., S&S of hepat. impairm., pre-exist.condits.assoc.with limit. hepat. funct. reserve, low leucocyte/neutrophil counts, meds.induc.bone marrow depress./toxic., bone marrow depress., hyper eosinophil.condits., myeloproliferat. dis., condits.contrib.core body temp. elevat., pts.at risk of aspirat.pneum., monit. high risk suic.pts., reg. BP monit.of pts.>65 yrs., grad. discont., velotabs.contain phenylalanine*

Drug interactions: *May antagon.effs.of levodopa & dopamine agonists, may enhanc.effs.of cert. anti hypertens., reduc.eff.with activat.charc., fluoxetine decr.clear., metabol.poss.induc.by carbamazepine low.plasma lev., clear.decr.by CYP1A2 inhibit.*

1.5.4 Others

ASPEN TRAZODONE, Aspen Pharmacare

See Section 1.4.10

CLOPIXOL, Lundbeck [P/S]

Zuclopenthixol decanoate.

Indications: *Maint.treatm.of schizophren. incl.agitat., psychomot.disturbs., hostility, suspicious., aggress., affect.react.*

(S5) DEPOT INJ, [P/S] R/2.6.5/52. 200 mg/ml.

714852-007: 1x1 ml, [R116,09](#)

714852-023: 5x1 ml, [R580,36](#)

Dosage: Admin.deep IMI

200-400 mg at 2-4 wk.intervals. Init:100 mg, 1 wk. later (or when sympts.recur but not more than 4 wks. later) 100-200 mg. Maint: 100-600 mg every 1-4 wks, usually 200 mg every 2-4 wks.

(S5) TABS, [P/S] T/2.6.5/180, 181.

Zuclopenthixol dihydrochloride.

Indications: *Behav.disturbs.in ac.& chron. schizophren., manic phase of bipol.affect.disord., ment.retardat.*

796751-005: 2 mg, 100, [R154,78](#)

789798-018: 10 mg, 100, [R385,60](#)

Dosage: Indiv.dos.

Ac.schizophren.& other ac.psychos., sev.ac. states of agit., mania: 10-50 mg/day. Mod.to sev.cases: Init. 20 mg/day incr.if necess.by 10-20 mg/day every 2-3 days to 75 mg.

Chron.schizophren.& other chron.psychos. Maint: Usually 20-40 mg/day.

Agitat.in oligophren.pts: 6-20 mg/day. If necess. incr.to 25-40 mg dly.

(S5) ACUPHASE INJ, [P/S] W/2.6.5/27.

Zuclopenthixol acet.

Indications: *Init.treatm.of ac.psychos.incl.mania, exacerbat.of chron.psychos.*

786934-018: 50 mg/ml, 1x1 ml amp, [R140,24](#)

Dosage: Admin. IMI.

Adults: Indiv.accord.to condit. Normal dos.range 50-150 mg, rep.if necess.with 2-3 day time interv. Few pts.may req.an addit.inj.24-48 hrs.follow.1st inj. Maint: Change to Clopixol Depot.

Contraindications: *Ac.alcoh., barbit./opiate intoxicat., hepat.dis., comat.states., preg.& lactat., dementia-relat. behav.disturbs., childr.*

Side effects: *Thrombocytopen., neutropen., leukopen., agranulocytosis, hypersens./anaphylact. reacts., hyperprolactinaem., incr/decr.appet., incr./decr. weight, hyperglycaem., imp.gluc.tol., hyperlipidaem., insomn., depress., anx., nervoun., abnorm. dreams, agit., incr/decr.libido, apathy, nightmares, confus.state, somnol, akathis., hyper-/hypokines., trem., dyston., hyperton., dizzin., headache, paraesthes., attent.disturbs., amnes., abnorm. gait, tard.dyskines., hyperreflex, dyskines., parkinson., syncope, atax., speech disord., hypoton., convuls., migraine, neurolept.malign. syndr., accommodat.disord., abnorm.vision., oculogyrat., mydriasis., vertigo, hyperacus., tinnit., tachycard., palpit., ECG QT prolong., hypotens., hot flush, ven.thromboembol., nasal congest., dyspn., GI disorders, abnorml LFT, cholestas.hepatit., jaund., hyperhidros., prurit., rash, photosens., pigmentat. disord., seborrh.dermatit., purpura, myalg., musc. rigid., trism., torticoll., micturit. disord., urin.retent., polyur., neonat.drug withdraw.syndr., ejaculat.fail, erect.dysfunct., fem.orgasm.disord., vulvovagin. dryn., gynaecomast., galactorrh., amenorrh., priapism, asthen., fatig., malaise, pain, thirst, hypotherm., pyrex., ventric.arrhythm./-fibrillat./-tachycard., Torsade de Pointes, sudd.unexplain. death. Depot & Acuphase: Inj.site reacts.*

Warnings and special precautions: *Neurolept. malign.syndr., convuls.disorders, advanc. hepat./ren./ CV dis., poss.dos.adjustm.of antidiabet.ther. as insul./gluc.respon.poss modif., monit.pts on long-term ther.& eval.periodic., pts.suscept.to QT prolongat./with CV disord. hist., concom.meds. known to incr.QT interval/risk of card.dysrhythm., avoid concom.anti-psychot.meds., identify poss VTE risk factors bef./dur.treatm.& undertake preventat. meas., stroke risk factors, older pts.with dementia, withdraw.sympts.with abrupt.discont., tabs. contain hydrogen.castor oil & may cause GI disturbs., use in pregn.3rd trimestr.poss. result in extrapyram./ withdraw.sympts in newborn., depot inj.with other meds.known to have myelosuppress. potent. Tabs: Lact.intol*

FLUANXOL DEPOT, Lundbeck [P/S]

Flupentixol decanoate.

Indications: Schizophren.**(S5) INJ.** G/2.6.5/138726672-004: 20 mg/ml, 1 x 1 ml, **R93,93**726672-025: 20 mg/ml, 5 x 1 ml, **R469,68****Dosage:** Deep IMI 20-60 mg every 2-4 wks. depend.on respons.**Contraindications:** *Extrem.excitab.& overactiv. pts., circulatory collapse, depress.consciousn., coma, pregn.& lactat., phaeochromocyt., bone marr. suppress.***Side effects:** *Extrapyramid.reacts., tard. dyskines., tachycard., palpitat., bld.dyscras., somnol., akathis., hyper-/hypokines., trem., dyston., dizzin., headache, tard.dyskines., dyskines., Parkinson., speech disord., convuls., NMS, accommodat. disord., abnorm.vis., oculogyrat., dyspn., GI disturbs., micturit.disord., urin. retent., neonat.**withdr.syndr., hyperhidros., prurit., skin rash, photosens., dermatit., myalg., musc. rigid., hyperprolactinaem., incr.appet.& weight, decr. appetit., hyperglycaem., abnorm.**gluc. tol., hypotens., hot flushes, ven. thromboembol., asthen., fatig., inj.site reacts., abnorm. LFT, jaund., ejaculat.fail., erect. dysfunct., gynaecomast., galactorrh., amenorrh., insomn., depress., nervousn., agitat., decr.libido, confus. state, QT prolongat., ventric.dysrhythm./-fibrillat./-tachycard., Torsade de Pointes, sudd.unexplain.**death, withdr.sympts.with sudd.discont.***Warnings and special precautions:** *Poss. developm. of neurolept.malign.syndr., incr. mortality with pre-exist.organ.brain.syndr./ment. retardat.& opiate and alcoh.abuse, eval longterm ther.to determ.maint.dos., indiv.suscept.to QT prolongat. & hist.of CV disord.eg.QT prolong./signif. bradycard./rec.ac.MI/uncompensat.HF & card.**dysrhythm.,avoid other concom.antipsychot. treatm., eval.VTE risk fact.& take prevent.meas., incr. CVA risk & incr.mortal.seen in dement. particip.in clinic.trials.with some antipsychot., stroke risk fact., do not use for dement.-relat. behav. disturbs., liv.& card.dis., dysrhythm., sev. resp.dis., ren.fail., epilep., Parkins.dis., narr. angle glauc., prostat.hypertrophy, hypo-/hyperthyroid., myasth.grav., thioxanthenes./ other antipsychot.hypersens., convuls., advanc. hepat.dis., modif.insul.& gluc.respons., reg. eye examinat., avoid sunlight expos., monit. haematolog. paramet.***Drug interactions:** *Sedat.effs.of alcoh.& CNS depress. enhanc., antihypertens.effs.eith.incr./reduc., incr.neurotox.risk with concom.Li, TCA & fluanxol depot inhib.metab.of one another, levodopa & adrenerg.effs.reduc., incr. extrapyramid. disord.with metoclopram.& piperazine, antipsychot.relat.QT interv.incr. exacerbat. by agents known to incr. QT interv., meds. known to cause electrol.disturbs./plasma conc. incr.flupentixol plasma conc.*

MOLIPAXIN, Sanofi-Aventis (Pty) Ltd

See Section 1.4.10**SULPIRIDE 50 OETHMAAN, (Equity)****Oethmaan Biosims [P/S]**

Sulpiride.

Indications: *React.depress.& depress.assoc.with psychos.of other origins, prophylax.& treatm.of depress. psychos., schizophren., ac.delir., ac. hallucinat. & confus.states, behav.disord., duod. ulc. ther.adjunct, vertigo.***(S5) CAPS,** U/2.6.5/32820199-028: 50 mg, 100, **R181,98****Dosage:** Elderly: Admin.in reduc.dos.**Psychiatry:****Mild psych.condits.of short.durat.& behav. disorders:** Adults: Init. 100-150 mg dly. up to 300 mg dly. in div.dos. Maint: Reduc./incr.as necess. Treatm.durat: as necess.Withdr.grad. **Sev.psych.disorders:**1200-1600 mg/day in div.dos. **Psychiatry:** Childr: 3-5 mg/kg bm.**Gastro-enterol:** Adults: 150-300 mg dly.in div. dos.**Vertigo:** Adults: 150-300 mg dly.x15-20 days.**Contraindications:** *Not recomm.in hypoman., manic or pre-manic phase of manic-depress. psychos., ac.mania, pre-exist.CNS depress./coma, phaeochromocyt., bone marr.depress., caut.in hypertens., not safe in ac.porphyr., safety in pregn. & lactat. not est.***Side effects:** *Freq: Akathis., ac.dyston., parkinson.-like syndr., tard.dyskines., dry mouth, nas. congest., constip., eye pigm.deposit.dur.longt. ther., blurr.vis., corn.opacit., postur.hypotens., hypertens. Less freq: CNS eff., cataton.-like state, EEG chang., convuls., temp.regul.dysfunct., mios., extrapyramid.sympt., NMS, perior.trem., micturit. diffic., photosens., mydrias., card.disord., SLE, skin pigment deposit.dur.prolong.ther., jaund., weight gain, reproduct.syst.disord.incl.priapism, bld. dyscras., potent.fatal agranulocytos. Unknown freq: Hyperglycaem., alt.gluc.tol., hypersens. reacts.incl.urticar./exfoli.dermatit./ erythema multiforme/cont.sens.***Warnings and special precautions:** *Psychot. suicid./tard.dyskines.risk, liv./ren./CV/ cerebrovasc./resp.impairm., clos.-angl.glauc., parkinson., diab.mellit., epilep., hypothyroid., myasth. grav., prostat.hypertrophy, avoid in untreat. epilep., elderly esp.with dement., debilit., eff.on vomit.centre poss.mask sympt.of other agents overdos./GI obstruct.disord., avoid. admin. dur.extreme temps., reg. eye exam.dur.longt.ther., direct sunl.expos., reg.haematolog.paramet.monit., abrupt withdr., lact.intol.***Interactions:** *Enhanc.CNS depress.eff.with other CNS depress.incl.alcoh./anaesthet., dos.adjustm. with other agents produc.postur.hypotens., antihypertens. eff.of guanethidine & other adrenerg. neur.block.poss.reduc., adverse eff.of other antimuscarin.meds.poss.potent.incl.TCA's/antimuscar.anti-parkinson.agents, poss.incr. extrapyramid. eff.with metoclopramide, incr. ventric. arrhythm.risk with halofantrine/anti-arrhythm./antihist./antimalar.agents/cisapride.*