ZOSTRACOL
Anastrozole tablets 1 mg
2067994

PROFESSIONELE INLIGTING VIR ZOSTRACOL

SKEDULERINGSTATUS:

S4

1 NAAM VAN DIE MEDISYNE
ZOSTRACOL (filmbedekte tablette)

2 KWALITATIEWE EN KWANTITATIEWE SAMESTELLING
Elke filmbedekte tablet bevat 1 mg anastrosool.
ZOSTRACOL bevat suiker (laktosemonohidraat)
Raadpleeg afdeling 6.1 vir die volledige lys van hulpstowwe.

3 FARMASEUTIESE VORM
Wit, ronde, bikonvekse, filmbedekte tablette met “1” op een kant gedruk en “H” op ander kant.

4. KLINIESE BESONDERHEDE
4.1 Terapeutiese indikasies
- **ZOSTRACOL** is aangedui vir die behandeling van vroeë metastatiese borskanker in postmenopousale vroue.
- **ZOSTRACOL** is aangedui vir die behandeling van gevorderde borskanker in postmenopousale vroue.
- Die doeltreffendheid is nie aangetoon in pasiënte wat estrogeenreseptornegatief is nie, tensy hulle ’n vorige positiewe kliniese reaksie op tamoksifeen gehad het.

4.2 Dosis en metode van aanwending
Volwassenes, waaronder bejaardes:
Een tablet van 1 mg een keer per dag per mond.

Spesiale populasies
Swak nierfunksie:
Geen aanpassing in die dosis vir pasiënte met ligte tot matige swak nierfunksie word aanbeveel nie.

Swak lewerfunksie:
Geen aanpassing in die dosis vir pasiënte met matige lewersiekte is nodig nie.

Pediatriese populasie:
Nie aanbeveel vir gebruik deur kinders nie.

Metode van toediening
ZOSTRACOL moet oraal gedrink word.

4.3 Kontra-indikasies
- Hipersensitiwiteit vir anastrosool of vir enige van die hulpstowwe van **ZOSTRACOL** (kyk afdeling 6.1).
- Swangerskap en borsvoeding (kyk afdeling 4.6).
- Premenopousale vroue.
- Pasiënte met erge swak nierfunksie (kreatinienopruiming minder as 20 ml/min) (kyk afdeling 4.4).
- Pasiënte met matige tot erge lewersiekte (kyk afdeling 4.4).

4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik
- Anastrosool moet nie aan premenopousale vroue gegee word nie (kyk afdeling 4.3). Die menopouse moet biochemies gedefinieer word (luteïniseringshormoon [LH], follikelstimulerende hormoon [FSH], en/of estradiolvlakke) in enige pasiënt waar daar twyfel oor menopousale status bestaan.
- Daar is geen data wat die gebruik van anastrosool met analoë van die luteïniseringshormoon-vrystellende hormoon (LHRH) ondersteun nie.
- Toediening van tamoksifeen of estrogeenbevattende middels saam met anastrosool moet vermy word aangesien dit die farmakologiese werking daarvan kan verminder (sien afdelings 4.5 en 5.1).
- Omdat **ZOSTRACOL** die vlakke van sirkulerende estrogeen verlaag kan dit ’n afname in beenmineraaldigtheid met gevolglike hoër risiko vir fraktures veroorsaak. Hierdie moontlike hoër risiko moet volgens die behandelingsriglyne vir beengesondheid in postmenopousale vroue bestuur word.
- Daar is geen data wat die veilige gebruik van **ZOSTRACOL** deur pasiënte met matige of erge swak lewerfunksie ondersteun nie, of pasiënte met erge swak nierfunksie (kreatinienopruiming minder as 20 ml/min) (kyk afdeling 4.3).

Laktose
- **ZOSTRACOL** bevat laktose. Pasiënte met die skaars oorerflike toestand van onverdraagbaarheid van galaktose, laktasetekort of wanabsorpsie van glukose/galaktose of met onverdraagbaarheid van fruktose, moet nie **ZOSTRACOL** drink nie.

Pediatriese populasie:
ZOSTRACOL word nie vir kinders of adolessente aanbeveel nie omdat die veiligheid en effektiwiteit vir hierdie groepe pasiënte nie bepaal is nie.

4.5 Interaksies met ander medisyne en ander vorms van interaksie
In studies van die interaksie met antipirien, warfarien en simetidien is getoon dat toediening van **ZOSTRACOL** saam met ander middels wat deur sitochroom P450 gemetaboliseer word, waarskynlik nie tot klinies beduidende interaksies sal lei nie.

Die databasis van veiligheid in kliniese proewe het geen getuienis van klinies beduidende interaksies in pasiënte wat met ZOSTRACOL behandel is en ook ander medisyne gekry het wat algemeen voorgeskryf word nie. Daar was geen klinies beduidende interaksies met bisfosfonate nie.

Tot op datum is daar geen kliniese inligting oor die gebruik van **ZOSTRACOL** saam met ander antikankermiddels nie.

Medisyne wat tamoksifeen en/of estrogeen bevat, moet nie saam met **ZOSTRACOL** gegee word nie omdat hulle die farmakologiese werking daarvan kan verlaag.

4.6 Fertiliteit, swangerskap en borsvoeding
Swangerskap
Daar is geen data oor die gebruik van **ZOSTRACOL** in swanger vroue nie. Studies met diere het toksisiteit op voortplanting aangetoon. **ZOSTRACOL** is teenaangedui tydens swangerskap (kyk afdeling 4.3)

Borsvoeding
Daar is geen data oor die gebruik van **ZOSTRACOL** tydens borsvoeding nie. **ZOSTRACOL** is teenaangedui vir vroue wat borsvoed (kyk afdeling 4.3).
Vrugbaarheid
Die effek van **ZOSTRACOL** op menslike vrugbaarheid is nie bestudeer nie.

4.7 Effek op vermoë om ’n voertuig te bestuur en masjiene te gebruik
ZOSTRACOL kan newe-effekte soos astenie en lomerigheid veroorsaak. Pasiënte moet aangeraai word om nie ’n voertuig te bestuur of masjiene te hanteer nie totdat dit vasgestel is dat hul vermoë om sulke aktiwiteite uit te voer nie geraak word nie.

4.8 Ongewensde effekte
a) Opsomming van die veiligheidsprofiel
Die mees algemene nadelige effekte van anastrosool is gastro-intestinale versteurings (waaronder anoreksie, naarheid, en braking en diarree), astenie, warm gloede, duiseligheid, lomerigheid, hoofpyn en uitslag. Ander algemeen aangemelde effekte is onder meer hare wat yler word, vaginale droogheid of bloeding, mialgie, artralgie, karpaletonnelsindroom en skeletbeenpyn. Slaaploosheid, depressie, perifere edeem, limfedeem, hoes, faringitis, dispnee, rugpyn en hipertensie is ook algemeen.

b) Lys van nadelige reaksies
Versteurings van die bloed en limfstelsel
Dikwels: limfedeem
Minder dikwels: anemie, leukopenie
Versteurings in metabolisme en voeding
Dikwels: anoreksie, hipercholesterolemie, swak eetlus

Psigiatriese versteurings
Dikwels: slaaploosheid, depressie
Minder dikwels: slaperigheid, angs

Versteurings van die immuunstelsel
Dikwels: hoofpyn, karpaletonnelsindroom, duiseligheid

Oogversteurings
Minder dikwels: katarakte

Vaskulêre versteurings
Dikwels: warm gloede, hipertensie
Minder dikwels: trombo-embolisme, tromboflebitis

Respiratoriese, toragiese en mediastinale versteurings
Dikwels: hoes meer, faringitis, dispnee
Minder dikwels: brongospasma, rinitis, sinusitis

Gastro-intestinale versteurings
Dikwels: naarheid, diarree, braking

Hepatobiliêre versteurings
Minder dikwels: hepatitis, hipercholesterolemie

Versteurings van die vel en subkutane weefsel
Dikwels: alopesie (hare word yl), uitslag, allergiese reaksies waaronder angioedeem, urtikarie en anafilakse
Minder dikwels: multivorme eriteem, Stevens-Johnsonsindroom

Versteurings van die muskuloskeletale stelsel, bindweefsel en skeletbene
Dikwels: artralgie (gewrigstyfheid), artritis, mialgie, skeletbeenpyn, beenfraktuur, osteoporose, rugpyn

Versteurings van die niere en urienweg
Minder dikwels: urienweginfeksies

Versteurings in die voortplantingstelsel en borste
Dikwels: vaginale droogheid, vaginale bloeding.
Kongenitale, familiale/genetiese versteurings
Dikwels: lomerigheid

Algemene versteurings en versteurings by die plek van toediening
Dikwels*:* astenie, perifere edeem

Ondersoeke
Minder dikwels: abnormaliteite in lewerensieme, styging in vlakke van alkaliese fosfatase, alanienaminotransferase en aspartaataminotransferase, in gamma-GT en bilirubien
c) Beskrywing van spesifieke nadelige reaksies
Voorvalle van karpaletonnelsindroom is aangemeld in pasiënte wat anastrosool ontvang het, en in groter getalle as dié wat behandeling met tamoksifeen gekry het. Die meeste van hierdie voorvalle was egter in pasiënte met identifiseerbare risikofaktore vir die ontwikkeling van die toestand.

Vaginale bloeding is gereeld aangemeld, veral deur pasiënte met gevorderde borskanker en gedurende die eerste paar weke na oorskakeling van bestaande hormonale terapie na behandeling met anastrosool. As bloeding voortduur, moet verdere evaluering oorweeg word.

Ervaring na bemarking
Die volgende nadelige reaksies is na bemarking geïdentifiseer en kan oorsaaklik met die gebruik van **ZOSTRACOL** verband hou. Omdat hierdie reaksies vrywillig uit ’n bevolking van onbekende grootte aangemeld word, is dit nie moontlik om die frekwensie daarvan akkuraat te skat nie.

Versteurings van die senustelsel
Frekwensie onbekend: lomerigheid

Versteurings van die vel en subkutane weefsel
Frekwensie onbekend: anafilaktiese reaksie

Muskuloskeletale stelsel, bindweefsel en skeletbene
Frekwensie onbekend: snellervinger
Versteurings in die voortplantingstelsel en borste
Vaginale bloeding

Pediatriese populasie:
Die farmakokinetika en veiligheid is nie in kinders bestudeer nie.

Aanmeld van vermeende nadelige reaksies
Dit is belangrik om vermeende nadelige reaksies wat na magtiging van die medisyne voorkom, aan te meld. Dit maak voortgesette monitering van die balans tussen voordeel en risiko vir die medisyne moontlik. Gesondheidsorgverskaffers word versoek om vermeende nadelige reaksies aan te meld die vorm “**6.04 Adverse Drug Reaction Reporting Form**” wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/publications/Index/8 of per epos aan die houer van registrasiesertifikaat: pvg.cdma@heterogroups.com

4.9 Oordosis
Daar is geen verslae waar ’n pasiënt ’n dosis van meer as 60 mg geneem het nie. Geen toksisiteit is waargeneem nie, en geen klinies relevante nadelige effekte is gesien nie.
’n Enkele dosis van **ZOSTRACOL** wat lewensbedreigende simptome kan veroorsaak, is nie bepaal nie.

Behandeling:
Daar is geen spesifieke teenmiddel teen oordosering nie en behandeling is simptomaties. Met die hantering van ’n oordosis moet die moontlikheid dat verskeie medisynes gedrink is in gedagte gehou word. Braking kan geïnduseer word as die pasiënt wakker is. Dialise kan nuttig wees omdat **ZOSTRACOL** nie tot ’n groot mate aan proteïene bind nie. Algemene ondersteunende sorg waaronder gereelde monitering van vitale tekens en noukeurige observasie van die pasiënt is aangedui.

5 FARMAKOLOGIESE EIENSKAPPE
5.1 Farmakokinetiese eienskappe
A 21.12 Hormoonremmers
Farmakoterapeutiese groep: Ensiemremmers
ATC-kode: L02B G03

Werkingsmeganisme
Anastrosool is ’n selektiewe niesteroïed aromataseremmer. Dit rem die omskakeling van androsteendioon na estroon deur die aromatase-ensiemkompleks in perifere weefsel te rem waar estroon daarna na estradiol omgeskakel word. in postmenopousale vroue gee anastrosool teen ’n daaglikse dosis van 1 mg meer as 80% onderdrukking van estradiol.
Anastrosool het geen progestogene, androgene of estrogene aktiwiteit nie.
Anastrosool het geen progestogene of androgene aktiwiteit nie.
Anastrosool het geen effek op afskeiding van kortisol of aldosteroon nie, soos gemeet voor of na ’n standaard ACTH-uitdaagtoets.

5.2 Farmakokinetiese eienskappe
Absorpsie
Absorpsie van anastrosool is vinnig en maksimum konsentrasies in die plasma word binne 2 uur na dosering onder vastende toestande bereik. Voedsel verlaag die tempo van absorpsie, maar nie die mate nie.

Verspreiding
In die terapeutiese gebied bind slegs 40% van die anastrosool aan plasmaproteïene.
Ongeveer 90 tot 95% van die gelykvlakkonsentrasies van anastrosool in plasma word ná 7 daaglikse dosisse bereik. Daar is geen getuienis dat die farmakokinetiese parameters van anastrosool van tyd of dosis afhanklik is nie.

Biotransformasie
Anastrosool word tot ’n groot mate deur postmenopausale vroue gemetaboliseer met minder as 10% van die dosis wat binne 72 uur na dosering onveranderd in die urien uitgeskei word. Anastrosool word deur N-dealkilering, hidroksilering en glukuronidering gemetaboliseer.

Uitskeiding
Uitskeiding van anastrosool is stadig met ’n plasmahalfleeftyd van 40 tot 50 uur. Die metaboliete word hoofsaaklik in die urien uitgeskei. Triasool, ’n belangrike metaboliet in plasma en urien, rem aromatase nie.
Die oënskynlike orale opklaring van anastrosool in vrywilligers met ligte stabiele lewersirrose of ligte swak nierfunksie was in dieselfde gebied as dié van gesonde persone.
Die farmakokinetika van anastrosool in postmenopousale vroue is onafhanklik van ouderdom.

Swak nier- of lewerfunksie
Dit is gemeld dat die oënskynlike opruiming (CL/F) van anastrosool, na orale toediening, ongeveer 30% laer was in vrywilligers met stabiele lewersirrose as in ooreenstemmende kontroles. Anastrosoolkonsentrasies in die plasma van vrywilligers met lewersirrose was egter binne die konsentrasiegebied wat in normale proefpersone in ander proewe gesien is. Anastrosoolkonsentrasies in plasma wat tydens proewe oor langtermyndoeltreffendheid in pasiënte met lewerversaking waargeneem is, was binne die gebied van anastrosoolkonsentrasies wat in plasma van pasiënte sonder lewerversaking gesien is.
Dit is gemeld dat die oënskynlike opruiming (CL/F) van anastrosool, na orale toediening, nie anders is in vrywilligers met erge nierversaking (GRF < 30 ml/min) nie, in ooreenstemming met die feit dat anastrosool hoofsaaklik deur metabolisme uitgeskei word. Anastrosoolkonsentrasies in plasma wat tydens proewe oor langtermyndoeltreffendheid in pasiënte met nierversaking waargeneem is, was binne die gebied van anastrosoolkonsentrasies wat in plasma van pasiënte sonder nierversaking gesien is. Toediening van anastrosool aan pasiënte met erge swak nierfunksie moet versigtig gedoen word (kyk afdeling 4.2 en 4.4).

Pediatriese populasie
Die farmakokinetika van anastrosool is nie in kinders bestudeer nie.

Omgewingsimpakstudies:
Anastrosool is ’n goed gevestigde aktiewe bestanddeel wat in farmaseutiese preparate deur mense gebruik word. Gegewe die verwagte patroon van gebruik en wegdoening van die produk, sal die blootstelling van die omgewing aan die aktiewe bestanddeel en metaboliete na verwagting baie beperk wees. Dit word nie geag dat die gebruik van anastrosool enige kommer oor omgewingskwessies voortbring of enige spesiale produketikettering vereis nie.

6 FARMASEUTIESE BESONDERHEDE
6.1 Lys van hulpstowwe
Tabletkern:
Isopropielalkohol
Magnesiumstearaat
Povidoon
Natriumstyselglikolaat

Bedekte tablet:
Opadry White (bestaan uit: hipromellose (E464), titaandioksied (E171) en makrogol-peg (E1521)

6.2 Onverenigbaarhede
Nie van toepassing nie.

6.3 Raklewe
36 maande

6.4 Spesiale voorsorgmaatreëls vir bewaring
Bêre teen of onder 25 °C. Beskerm teen lig en vog.
Hou die stulpstroke in die karton totdat dit benodig word.
HOU BUITE BEREIK VAN KINDERS.

6.5 Aard en inhoud van die houer
Gewone silwer-aluminium stulpstroke as ’n dekfoelie verseël met die gewone silwer-aluminium/helder PVC stulpstroke as ’n vormingsfoelie wat 10 tablette per stulpstrook bevat wat in ’n kartonhouer verpak is.

Pakgroottes: 30 filmbedekte tablette per pak.
Hou die stulpstroke in die karton totdat dit benodig word.

6.6 Spesiale voorsorgmaatreëls vir wegdoening en ander hantering
Geen spesiale vereistes nie.

7 HOUER VAN DIE REGISTRASIESERTIFIKAAT
Hetero Drugs South Africa (Edms) Bpk
Jean Park Chambers
Jeanlaan 252
Gebou 6, Eenhede 17 & 18
Centurion, 0157

8. REGISTRASIENOMMER(S)
47/21.12/0506

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PASIëNTINLIGTINGSBLAD VAN ZOSTRACOL

SKEDULERINGSTATUS

S4

ZOSTRACOL 1 mg (filmbedekte tablette)
Elke filmbedekte tablet bevat 1 mg anastrosool.

ZOSTRACOL bevat suiker (laktosemonohidraat)

Lees hierdie hele blad noukeurig deur voordat u begin om ZOSTRACOL te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vrae het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- **ZOSTRACOL** is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s’n.

Wat in hierdie blad is

1. Wat ZOSTRACOL is en waarvoor dit gebruik word
- **ZOSTRACOL** behoort aan ’n groep medisyne bekend as hormoonremmers. Dit beteken dat dit inmeng met sommige van die werkings van aromatase, ’n ensiem in die liggaam wat die vlak van sekere vroulike geslagshormone soos estrogeen beïnvloed.
- **ZOSTRACOL** word gebruik om vroeë en gevorderde borskanker te behandel in vroue wat deur menopouse gegaan het (postmenopousaal).
- **ZOSTRACOL** word gebruik om pasiënte met borskanker, selfs na behandeling met tamoksifeen, te behandel.

2. Wat u moet weet voordat u ZOSTRACOL drink
Moenie ZOSTRACOL drink nie:
- as u hipersensitief (allergies) vir anastrosool of vir enige van die ander bestanddele van **ZOSTRACOL** (gelys in afdeling 6) is
- as u swanger is of u baba borsvoed (kyk “**Swangerskap, borsvoeding en vrugbaarheid**”).
- as u nog menstrueer en nog nie in menopouse is nie (premenopousaal).
- as u ’n erge niersiekte het.
- as u matige of erge lewersiekte het.

Waarskuwings en voorsorgmaatreëls
Wees besonder versigtig met ZOSTRACOL:
- as u ’n geskiedenis van beenfrakture of ’n toestand het wat die sterkte van u skeletbene aantas (osteoporose).
- as u medisyne gebruik wat tamoksifeen bevat of medisyne wat estrogeen bevat (kyk “**Ander medisyne en ZOSTRACOL**”).

Aangesien **ZOSTRACOL** nie vir premenopousale vroue gebruik word nie, kan u dokter sekere toetse doen om te bevestig dat u postmenopousaal is.

Kinders en adolessente
ZOSTRACOL moet nie vir kinders gegee word nie.

Ander medisyne en ZOSTRACOL
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).

Sê vir u dokter of apteker indien u enige van die volgende middels gebruik:
- Sekere medisyne om borskanker te behandel (selektiewe estrogeenreseptormoduleerders), bv. medisyne wat tamoksifeen bevat. Dit is omdat hierdie medisyne **ZOSTRACOL** kan keer om behoorlik te werk.
- Estrogeenbevattende medisyne (soos hormoonvervangingsterapie).

ZOSTRACOL saam met voedsel en drank
ZOSTRACOL kan met of sonder voedsel gedrink word. Voedsel sal **ZOSTRACOL** nie beïnvloed nie.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om ’n baba te hê, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg voordat u hierdie medisyne gebruik.
Moenie **ZOSTRACOL** drink as u swanger is of u baba borsvoed nie. As u swanger raak terwyl u **ZOSTRACOL** gebruik, moet u dadelik met **ZOSTRACOL** ophou en u dokter raadpleeg.

Motorbestuur en gebruik van masjinerie
ZOSTRACOL kan u vermoë om ’n voertuig te bestuur of masjinerie te gebruik aantas. U mag dalk swak of slaperig voel terwyl u **ZOSTRACOL** drink. Totdat u weet hoe **ZOSTRACOL** u affekteer, moet u nie ’n voertuig bestuur, masjinerie hanteer of enigiets doen wat gevaarlik kan wees nie.

ZOSTRACOL bevat laktosemonohidraat (’n tipe suiker)
As u dokter dus vir u gesê het dat u ’n onverdraagbaarheid teenoor sekere suikers het, moet u u dokter skakel voordat u hierdie medisyne drink.

3. Hoe om ZOSTRACOL te drink
Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Drink **ZOSTRACOL** altyd presies soos wat u dokter of apteker vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie.
Die gewone dosis is een tablet (1 mg) een keer per dag.
Probeer om u tablette elke dag op dieselfde tyd te drink.
Sluk die tablet heel met water af.
U kan **ZOSTRACOL** met of sonder kos drink (kyk “**ZOSTRACOL saam met voedsel en drank**”).
U dokter sal vir u sê hoe lank u behandeling met **ZOSTRACOL** sal duur. U moet behandeling nie voortydig stop nie, want dit is ’n langtermynbehandeling en u sal dit dalk vir ’n lang tyd moet drink. Sê vir u dokter of apteker as u die indruk het dat die effek van **ZOSTRACOL** te sterk of te swak is.

As u meer ZOSTRACOL gedrink het as wat u moes
Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet het om ZOSTRACOL te drink
As u u dosis met slegs ’n paar uur gemis het, drink die oorgeslane dosis sodra u onthou. As dit bykans tyd vir u volgende dosis is, los die oorgeslane dosis en drink **ZOSTRACOL** op die volgende gewone geskeduleerde tyd.
Moenie ’n dubbele dosis drink om vir die vergete individuele dosisse op te maak nie.

As u ophou om ZOSTRACOL te drink
Moenie ophou om u tablette te drink nie tensy u dokter vir u sê om dit te doen.

4. **MOONTLIKE NEWE-EFFEKTE**
ZOSTRACOL kan newe-effekte veroorsaak.
Nie al die newe-effekte wat vir **ZOSTRACOL** aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u enige newe-effekte ervaar terwyl u **ZOSTRACOL** drink, moet u u dokter, apteker of ander gesondheidsorgverskaffer om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om ZOSTRACOL te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:
- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
- veluitslag of jeuk
- floutes

Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u ’n ernstige reaksie op **ZOSTRACOL** gehad het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:
Dikwels*:*
- swelling van die onderbene en hande
- beenverlies (osteoporose)
- hoë bloeddruk
- boonstelugweginfeksie (keelinfeksie)
- beenfrakture
- hoër of hoë vlakke van ’n vetterige stof bekend as cholesterol in die bloed. Dit sal in ’n bloedtoets gesien word.
- pyn in die buik
- bloed in die urien
- geel verkleuring van die vel of wit van die oë (geelsug)
- kortasemheid of moeilike asemhaling
- hartaanval
- pyn in die borskas
- onreëlmatige hartklop
- groei van gesighare
- swelling en teerheid van die borste
- laer seksdrif

Minder dikwels:
- bloeding van die vagina
- inflammasie van die lewer (hepatitis)
- seldsame inflammasie van die vel wat rooi kolle of blase kan insluit (Stevens-Johnsonsindroom)
- veluitslag veroorsaak deur hipersensitiwiteit (dit kan van ’n allergiese of anafilaktoïede reaksie wees)
- bloedselafwykings (anemie of leukopenie)
- katarakte (vertroebeling van die lens in die oog wat tot ’n afname in visie lei)
- obstruksie van die bloedvate (trombo-embolisme), inflammasie van bloedvate (tromboflebitis)
- plaaslike swelling van die vel (urtikarie)

Hierdie is almal ernstige newe-effekte. Dit mag wees dat u dringende mediese aandag nodig het.

Sê so gou as moontlik vir u dokter as u enige van die volgende opmerk:
Dikwels:
- hoofpyn
- gloede
- naarheid (voel mislik)
- veluitslag
- pyn of styfheid in die gewrigte, spierpyn, beenpyn, rugpyn
- hoofpyn, duiseligheid, lomerigheid
- slaaploosheid
- verlies aan eetlus
- depressie
- karpaletonnelsindroom (pyn, gevoelloosheid en tinteling, in die duim, wysvinger, middelvinger en die duimkant van die ringvinger)
- diarree
- haarverlies
- hoes
- vaginale droogheid

Minder dikwels:
- braking (bring op)
- ’n immuunreaksie van die vel wat deur ’n infeksie of medikasie veroorsaak kan word (multivorme eriteem)

As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte
Dit is belangrik om vermeende nadelige reaksies wat na magtiging van die medisyne voorkom, aan te meld. Dit maak voortgesette monitering van die balans tussen voordeel en risiko vir die medisyne moontlik. Verskaffers van gesondheidsorg word versoek om vermeende nadelige reaksies by SAHPRA aan te meld met die vorm “**6.04 Adverse Drug Reaction Reporting Form**” wat aanlyn by SAHPRA se publikasies gekry kan word by https://www.sahpra.org.za/publications/Index/8 of per epos aan die houer van die registrasiesertifikaat by pvg.cdma@heterogroups.com.

5. Hoe om ZOSTRACOL te bêre
Hou alle medisyne buite bereik van kinders.
Bêre by of onder 25 °C.
Hou die stulppak in die karton totdat dit vir gebruik benodig word.
Beskerm teen lig en vog.
Daar is geen spesiale bewaringsinstruksies vir **ZOSTRACOL** nie.
Moenie in ’n badkamer bêre nie.
Moenie na die vervaldatum op die etiket/karton gebruik nie.
Gee alle ongebruikte medisyne terug aan u apteker.
Moenie ongebruikte medisyne in dreinering- of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting
Wat ZOSTRACOL bevat
- Die aktiewe bestanddeel is anastrosool.
- Die ander bestanddele is laktosemonohidraat, magnesiumstearaat, povidoon, natriumstyselglikolaat, Opadry White Y-1-7000 (bevat hipromellose, makrogol, titaandioksied).

Hoe ZOSTRACOL lyk en die inhoud van die pak
ZOSTRACOL is wit, ronde, bikonvekse, filmbedekte tablette met “1” op een kant gedruk en “H” op ander kant.

Inhoud van die verpakking
Stulppakke
Pak met 30: ZOSTRACOL is verpak in gewone silwer-aluminium/helder PVC stulpstroke met 10 tablette elk. Pakgroottes: 10 filmbedekte tablette per stulpstrook. 10 x 3 stulpstroke is in ’n boks verpak.
Stulpstroke is in ’n kartonboks verpak.

Houer van die registrasiesertifikaat
Hetero Drugs South Africa (Edms) Bpk
Jean Park Chambers
Jeanlaan 252
Gebou 6, Eenhede 17 & 18
Centurion, 0157

Hierdie blad is laas hersien in
05 Oktober 2021

Registrasienommer
47/21.12/0506

Toegang tot die toepaslike professionele inligting
Hetero Drugs South Africa (Edms) Bpk
Jean Park Chambers
Jeanlaan 252
Gebou 6, Eenhede 17 & 18
Centurion, 0157

HETERO	ARTWORK SPECIFICATION		
Product Name	ZOSTRACOL		
Dimensions	500 x 750 mm		
Length	500 mm		
Width	750 mm		
Folding size	60 x 38 mm		
Grammage (GSM)	40		
Pharma Code No.	7994		
Braille	☐ Applicable ☑ Not Applicable		
Colours	BLACK ■		
Non printing colors	NA		
SPEC:	40 GSM Bible paper, Front and back side printing		
If Any	Pharma code position and Orientation are tentative, will be changed according to printers requirment to suit pharmacode position at center after folding.		
Initiator	**Reviewer**	**Marketing**	**DRP/RP**
16-05-2022	16-05-2022	V.van der Linde 16/05/2022	17/05/2022

VERSION 02. 16 May 2022. Sent From India to SA	
Changes Made	**Customer provided corrections are updated**

PROFESSIONAL INFORMATION FOR ZOSTRACOL

SCHEDULING STATUS:

S4

1 NAME OF THE MEDICINE
ZOSTRACOL (film coated tablets)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each film coated tablet contains 1 mg anastrozole.
ZOSTRACOL contains sugar (lactose monohydrate)
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM
White colored, round shaped biconvex, film coated tablets, debossed with '1' on one side and 'H' on the other side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
- **ZOSTRACOL** is indicated for the treatment of early breast cancer in postmenopausal women.
- **ZOSTRACOL** is indicated for the treatment of advanced breast cancer in postmenopausal women.
- Efficacy has not been demonstrated in estrogen receptor negative patients unless they have had a previous positive clinical response to tamoxifen.

4.2 Posology and method of administration
Adults including the elderly:
One 1 mg tablet to be taken orally once daily.

Special populations
Renal impairment:
No dose change is recommended in patients with mild or moderate renal impairment.

Hepatic impairment:
No dose change is recommended in patients with mild hepatic disease.

Paediatric population:
Not recommended for use in children.

Method of administration
ZOSTRACOL should be taken orally

4.3 Contraindications
- Hypersensitivity to anastrozole or to any of the excipients of **ZOSTRACOL** (see section 6.1).
- Pregnancy and lactation (see section 4.6).
- Pre-menopausal women.
- Patients with severe renal impairment (creatinine clearance less than 20 ml/min) (see section 4.4).
- Patients with moderate or severe hepatic disease (see section 4.4).

4.4 Special warnings and precautions for use
- Anastrozole should not be used in premenopausal women (see section 4.3). The menopause should be defined biochemically (luteinizing-hormone [LH], follicle stimulating hormone [FSH], and/or estradiol levels) in any patient where there is doubt about menopausal status.
- There are no data to support the use of anastrozole with luteinizing hormone-releasing hormone (LHRH) analogues.
- Co-administration of tamoxifen or estrogen-containing therapies with anastrozole should be avoided as this may diminish its pharmacological action (see sections 4.5 and 5.1).
- As **ZOSTRACOL** lowers circulating estrogen levels it may cause a reduction in bone mineral density with a consequent increased risk of fracture.This possible increased risk should be managed according to treatment guideline for bone healthy in postmenopausal women.
- There are no data to support the safe use of **ZOSTRACOL** in patients with moderate or severe hepatic impairment, or patients with severe impairment of renal function (creatinine clearance less than 20 ml/min). (See section 4.3)

Lactose
- **ZOSTRACOL** contains lactose. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosaemia, lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take **ZOSTRACOL**

Paediatric population:
ZOSTRACOL is not recommended for use in children and adolescents as safety and efficacy have not been established in this group of patients.

4.5 Interaction with other medicines and other forms of interaction
Antipyrine, warfarin and cimetidine clinical interaction studies indicate that the co-administration of **ZOSTRACOL** with other medicines is unlikely to result in clinically significant medicine interactions mediated by cytochrome P450.

A review of the clinical trial safety database did not reveal evidence of clinically significant interaction in patients treated with anastrazole, as contained in **ZOSTRACOL** who also received other commonly prescribed medicines. There were no clinically significant interactions with biphosphonates.

There is no clinical information to date on the use of **ZOSTRACOL** in combination with other anti-cancer medicines.

Tamoxifen and/or estrogen-containing therapies should not be co-administered with **ZOSTRACOL** as they would diminish its pharmacological action.

4.6 Fertility, pregnancy and lactation
Pregnancy
There is no data on the use of **ZOSTRACOL** in pregnant woman. Studies in animals have shown reproductive toxicity. **ZOSTRACOL** is contraindicated during pregnancy (see section 4.3).

Breastfeeding
There is no data on the use of **ZOSTRACOL** during lactation. **ZOSTRACOL** is contraindicated in lactating women (see section 4.3).

Fertility
The effects of **ZOSTRACOL** on fertility in humans have not been studies.

4.7 Effects on ability to drive and use machines
ZOSTRACOL may cause side effects such as asthenia and somnolence. Patients should be advised not to drive or operate machines until it is established that their ability to perform such activities is not affected.

4.8 Undesirable effects
a) Summary of the safety profile
The most frequent adverse effects of anastrozole are gastro intestinal disturbances (including anorexia, nausea, and vomiting and diarrhoea) asthenia, hot flushes, dizziness, drowsiness, headache and rash. Other commonly reported effects include hair thinning, vaginal dryness or bleeding, myalgia, arthralgia, carpel tunnel syndrome, and bone pain. Insomnia, depression, peripheral oedema, lymphoedema. increased cough, pharyngitis, dyspnoea, back pain, and hypertension are also common.

b) Listing of adverse reactions
Blood and the lymphatic system disorders:
Frequent: Lymphoedema
Less frequent: Anaemia, leukopenia
Metabolism and nutrition disorders
Frequent: anorexia, hypercholesterolaemia, decreased appetite

Psychiatric disorders
Frequent: Insomnia, depression
Less frequent: Somnolence, anxiety

Nervous system disorders
Frequent: Headache, carpal tunnel syndrome, dizziness

Eye disorders
Less frequent: Cataracts

Vascular disorders
Frequent: Hot flushes, hypertension
Less frequent: Thromboembolism, thrombophlebitis

Respiratory, thoracic and mediastinal disorders
Frequent: Increased cough, pharyngitis, dyspnoea
Less frequent: Bronchitis, rhinitis, sinusitis

Gastrointestinal disorders
Frequent: Nausea, diarrhoea, vomiting

Hepato-biliary disorders
Less frequent: Hepatitis, hypercholesterolaemia

Skin and subcutaneous tissue disorders
Frequent: Alopecia (hair thinning), rash, allergic reactions including angioedema, urticaria and anaphylaxis
Less frequent: Eryhema multiformae, Stevens-Johnson syndrome

Musculoskeletal, connective tissue and bone disorders
Frequent: Arthralgia (joint stiffness), arthritis, myalgia, bone pain, bone fracture, osteoporosis, back pain

Renal and urinary disorders
Less frequent: Urinary tract infections

Reproductive system and breast disorders
Frequent: Vaginal dryness, vaginal haemorrhage

Congenital and familial/genetic disorder
Frequent: Drowsiness

General disorders and administrative site conditions
Frequent: Asthenia, peripheral oedema

Investigations
Less frequent: Hepatic enzyme abnormalities, Increase in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, increase in gamma-GT and bilirubin

c) Description of selected adverse reactions
Events of Carpal Tunnel Syndrome have been reported in patients receiving anastrozole treatment greater numbers than those receiving treatment with tamoxifen. However, the majority of these events occurred in patients with identifiable risk factors for the development of the condition.

Vaginal bleeding has been reported commonly, mainly in patients with advanced breast cancer during the first few weeks after changing from existing hormonal therapy to treatment with anastrozole. If bleeding persists, further evaluation should be considered.

Post-marketing
The following adverse reactions have been identified from post marketing experience and may be causally related to the use of **ZOSTRACOL**. Because these reactions have been reported voluntarily from a population of uncertain size it is not possible to accurately estimate their frequency.

Nervous system disorder:
Frequency unknown: somnolence

Skin and subcutaneous tissue disorders
Frequency unknown: anaphylactoid reaction

Musculoskeletal, connective tissue and bone:
Frequency unknown: trigger finger
Reproductive system and breast disorder:
vaginal bleeding

Paediatric population:
Pharmacokinetics and safety have not been studied in children.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/publications/Index/8 or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com .

4.9 Overdose
There are no reports where a patient has taken a dose excessing 60 mg. No toxicity was observed, and no clinically relevant adverse effects have been seen.
A single dose of **ZOSTRACOL** that results in life threatening symptoms has not been established.
Treatment:
There is no specific antidote to overdosage and treatment must be symptomatic. In the management of an overdose, consideration should be given to the possibility that multiple medicines may have been taken. Vomiting may be induced if the patient is alert. Dialysis may be helpful because **ZOSTRACOL** is not highly protein bound. General supportive care, including frequent monitoring of vital signs and close observation of the patient, is indicated.

5 PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
A 21.12 Hormone Inhibitors
Pharmacotherapeutic group: Enzyme inibitors
ATC code: L02B G03

Mechanism of action:
Anastrozole is a selective non-steroidal aromatase inhibitor. It inhibits the conversion of androstenedione to oestrone through the aromatase enzyme complex in peripheral tissues where oestrone is subsequently converted to estradiol. In postmenopausal women, anastrozole at a daily dose of 1 mg produced estradiol suppression of greater than 80 %.
Anastrozole does not possess any progestogenic, androgenic or estrogenic activity.
Anastrozole does not possess progestogenic, androgenic activity
Anastrozole does not have any effect on cortisol or aldosterone secretion, measured before or after testing standard ACTH challenge testing.

5.2 Pharmacokinetic properties:
Absorption
Absorption of anastrozole is rapid and maximum plasma concentrations occur after 2 hours of dosing under fasted conditions. Food decreases the rate but not the extent of absorption.

Distribution
Anastrozole is only 40 % bound to plasma proteins in the therapeutic range.
Approximately 90 to 95 % of plasma anastrozole steady-state concentrations are attained after 7 daily doses. There is no evidence of time or dose-dependency of anastrozole pharmacokinetic parameters.

Biotransformation
Anastrozole is extensively metabolised by postmenopausal women with less than 10 % of the dose excreted in the urine unchanged within 72 hours of dosing. Metabolism of anastrozole occurs by N-dealkylation, hydroxylation and glucuronidation.
Elimination
Anastrozole is eliminated slowly with a plasma elimination half-life of 40 to 50 hours. The metabolites are excreted primarily via the urine. Triazole, a major metabolite in plasma and urine, does not inhibit aromatase.

The apparent oral clearance of anastrozole in volunteers with mild stable hepatic cirrhosis or mild renal impairment was in the range has been reported
Anastrozole pharmacokinetics are independent of age in postmenopausal woman.
Renal or hepatic impairment
It has been reported that the apparent clearance (CL/F) of anastrozole, following oral administration, was approximately 30 % lower in volunteers, with stable hepatic cirrhosis than in matched controls. However, plasma anastrozole concentrations in the volunteers with hepatic cirrhosis were within the range of concentrations seen in normal subjects in other trials. Plasma anastrozole concentrations observed during long-term efficacy trials in patients with hepatic impairment were within the range of plasma anastrozole concentrations seen in patients without hepatic impairment.

It has been reported that the apparent clearance (CL/F) of anastrozole, following oral administration, was not altered in volunteers with severe renal impairment (GRF< 30 ml/min), consistent with the fact that anastrozole is eliminated primarily by metabolism. Plasma anastrozole concentrations observed during long-term efficacy trials in patients with renal impairment were within the range of plasma anastrozole concentrations see in patients without renal impairment. In patients with severe renal impairment, administration of anastrozole should be performed with caution (see section 4.2 and 4.4)

Paediatric population
Anastrozole pharmacokinetics have not been studied in children

Environmental Risk Assessment:
Anastrozole is a well-established active ingredient used in pharmaceutical preparations for human use. Given the anticipated pattern of use and disposal of the product, the environmental exposure of the active substance and metabolites are expected to be very limited. The use of Anastrozole is not considered warranting any environmental concerns or requiring any special product labeling.

6 PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Core Tablets:
Isopropyl alcohol
Magnesium stearate
Povidone
Sodium starch Glycolate

Coated Tablet:
Opadry white (made up of: Hypromellose (E 464), Titanium Dioxide (E 171) and Macrogol peg (E 1521)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at or below 25 °C. Protect from light and moisture.
Keep the blisters in the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container
Plain silver aluminium blister strips as a lidding foil sealed with the plain silver aluminium/clear PVC blister strips as a forming foil containing 10 tablets per blister packed in an outer cardboard carton.

Pack sizes: 30 film coated tablets per pack.
Keep the blister in outer carton until required for use.

6.6 Special precautions for disposal and other handling
No special requirements

7 HOLDERS OF CERTIFICATE OF RIGISTRATION
Hetero Drugs South Africa Pty) Ltd,
Jean Park Chambers
252 Jean Avenue
Building 6, Unit 17 & 18
Centurion 0157

8 REGISTRATION NUMBER(S)
47/21.12/0506

9 DATE OF PUBLICATION OF THIS PACKAGE INSERT:
05 October 2021

PATIENT INFORMATION LEAFLET ZOSTRACOL

SCHEDULING STATUS:

S4

ZOSTRACOL 1 mg (film coated tablets)
Each film coated tablet contains 1 mg anastrozole

ZOSTRACOL contains sugar (lactose)

Read all of this leaflet carefully before you start taking ZOSTRACOL
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **ZOSTRACOL** has been prescribed for you personally and you shou ld not share your medicine with other people. It may harm them,even if their symptoms are the same as yours.a

What is in this leaflet

1. What ZOSTRACOL is and what it is used for
- **ZOSTRACOL** belongs to a group of medicines called aromatase in hibitors. This means that it interferes with some of the actions of aro matase, an enzyme within the body which effects the level of certain female sex hormones such as estrogens.
- **ZOSTRACOL** is used to treat early and advanced breast cancer in women who have gone through menopause (post-menopausal).
- **ZOSTRACOL** is used to treat patient with breast cancer even after tamoxifen treatment.

2. What you need to know before you take ZOSTRACOL
Do not take ZOSTRACOL:
- If you are hypersensitive (allergic) to anastrozole or any of the other ingredients of **ZOSTRACOL** (listed in section 6).
- If you are pregnant or breastfeeding your baby (see **"Pregnancy, breastfeeding and fertility"**)
- If you still get your menstrual periods and have not gone through menopause yet (pre-menopausal).
- If you have a severe kidney disease.
- If you have moderate or severe liver disease.

Warnings and precautions
Take special care with ZOSTRACOL:
- If you have a history of bone fracture or have a condition that affects the strength of your bones (osteoporosis).
- if you are taking a medicine that contains tamoxifen or medicines that contain estrogen (see **"Other medicines and ZOSTRACOL"**)

As **ZOSTRACOL** is not for use in premenopausal women, your doctor may do some tests to confirm that you are postmenopausal.

Children and adolescents
ZOSTRACOL should not be given to children.

Other medicines and ZOSTRACOL
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

Also, tell your doctor or pharmacist if you are taking any of the following medicines:
- Certain medicines used to treat breast cancer (selective estrogen receptor modulators), e.g. medicines that contain tamoxifen. This is because these medicines may stop **ZOSTRACOL** from working properly.
- Estrogen containing medicines (such as Hormone Replacement Therapy).

ZOSTRACOL with food and drink
ZOSTRACOL can be taken with or without food. Food will not affect **ZOSTRACOL.**

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
Do not take **ZOSTRACOL** is you are pregnant or breastfeeding your baby. If you become pregnant while taking **ZOSTRACOL**, stop taking **ZOSTRACOL** and consult your doctor immediately.

Driving and using machines
ZOSTRACOL may impair your ability to drive and use machinery. You may feel weak or sleepy while taking **ZOSTRACOL**. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **ZOSTRACOL** affects you.

ZOSTRACOL contains lactose (a type of sugar)
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take ZOSTRACOL
Do not share medicines prescribed for you with any other person.
Always take **ZOSTRACOL** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

The usual dose is one tablet (1 mg) daily.
Try to take your tablet at the same time each day.
Swallow the tablet whole with a drink of water.
You can take **ZOSTRACOL** with or without food (see **"Taking ZOSTRACOL with food and drink"**).

Your doctor will tell you how long your treatment with **ZOSTRACOL** will last. Do not stop treatment early because it is a long-term treatment and you may need to take it for a long time. If you have the impression that the effect of **ZOSTRACOL** is too strong or too weak, tell your doctor or pharmacist.

If you take more ZOSTRACOL than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take ZOSTRACOL than you should
If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take **ZOSTRACOL** at the next regularly scheduled time.
Do not take a double dose to make up for forgotten individual doses.

If you stop taking ZOSTRACOL
Do not stop taking your tablets unless your doctor tells you to.

4. POSSIBLE SIDE EFFECTS
ZOSTRACOL can have side effects
Not all side effects reported for **ZOSTRACOL** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **ZOSTRACOL** please consult your health care provider for advice.

If any of the following happens, stop taking ZOSTRACOL and tell your doctor immediately or go to the casualty department at your nearest hospital:
- 'swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing',
- 'rash or itching',
- 'fainting'.

These are all very serious side effects. If you have them, you may have had a serious reaction to **ZOSTRACOL**. You may need urgent medical attention or hospitalisation.
Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
Frequent:
- Swelling of your lower legs and hands
- Bone loss (Osteoporosis)
- High blood pressure
- Upper respiratory infection (throat infection)
- Bone fracture
- Raised or high levels of a fatty substance known as cholesterol in your blood. This would be seen in a blood test
- Pain in your abdomen
- Blood in your urine
- Yellowing of the skin or whites of your eyes (jaundice)
- Shortness of breath or trouble breathing
- Heart attack
- Chest pain
- Irregular heart beats
- Growth of facial hair
- Swelling and tenderness of your breasts
- Reduced sex drive

Less frequent:
- Bleeding of the vagina
- Inflammation of the liver (hepatitis)
- Rare inflammation of your skin that may include red patches or blisters (Stevens-Johnson syndrome)
- Skin rash caused by hypersensitivity (this can be from allergic or anaphylactoid reaction)
- Blood cell abnormalities (anaemia or leukopenia)
- Cataracts (a clouding of the lens in the eye which leads to a decrease in vision)
- Obstruction of the blood vessels (thromboembolism), inflammation of blood vessels (thrombophlebitis)
- Local swelling of the skin(Urticaria)

These are all serious side effects. You may need urgent medical attention.

Tell your doctor as soon as possible if you notice any of the following:
Frequent:
- Headache
- Hot flushes
- Feeling sick (nausea)
- Skin rash
- Pain or stiffness in your joints, muscle pain, bone pain, back pain
- Weakness, dizziness, drowsiness
- Sleeplessness
- Loss of appetite
- Depression
- Carpal tunnel syndrome (pain, numbness, and tingling, in the thumb, index finger, middle finger, and the thumb side of the ring fingers)
- Diarrhoea
- Hair loss
- Cough
- Vaginal dryness

Less frequent:
- Getting Sick (Vomiting)
- A skin immune reaction that an infection or medication can trigger (Erythema multiforme)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/publications/Index/8 or to the Holder of certificate of registration through the mail: pvg.cdma@heterogroups.com.

5. How to store ZOSTRACOL
Store all medicines out of reach of children.
Store at or below 25 °C.
Keep the blister pack in the outer carton, until required for use.
Protect from light and moisture.
There are no special storage instructions for **ZOSTRACOL**.
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicines in drains or sewerage system (e.g. toilets).

6. Contents of the pack and other confirmation
What ZOSTRACOL contains
- The active substance is anastrozole.
- The other ingredients are lactose monohydrate, magnesium stearate, povidone, sodium starch glycolate, opadry white Y-1-7000 (containing hypromellose, macrogol, titanium dioxide).

What ZOSTRACOL looks like and contents of the pack
ZOSTRACOL looks like
White colored, round shaped biconvex, film coated tablets, debossed with '1' on one side and 'H' on the other side.

Contents of the pack
Blister pack
30's: ZOSTRACOL are packed in plain silver aluminium/clear PVC blister strips of 10 tablets each. Pack sizes: 10 film coated tablets per blister. 10 X 3 blisters packed in a box.

Blister packs are enclosed in an outer carton box.

Holder of Certificate of Registration
Hetero Drugs South Africa (Pty) Ltd,
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Centurion 0157.

This leaflet was last revised in
05 October 2021

Registration number
47/21.12/0506

Access to the corresponding Professional Information
Hetero Drugs South Africa (Pty) Ltd,
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2067694