**SCHEDULING STATUS:**

S4

**PROPRIETARY NAME (and dosage form):**

## NIDASALL 200 (Tablets)
## NIDASALL 400 (Tablets)

**COMPOSITION:**
**NIDASALL 200:** Each tablet contains metronidazole 200 mg
**NIDASALL 400:** Each tablet contains metronidazole 400 mg

**PHARMACOLOGICAL CLASSIFICATION:**
A 20.2.6 - Medicines against protozoa

**PHARMACOLOGICAL ACTION:**
Metronidazole has anti-protozoal activity against Trichomonas vaginalis, Entamoeba histolytica and Giardia lamblia. Metronidazole has bactericidal activity *in vitro* against several anaerobic organisms.

**INDICATIONS:**
1. Trichomonas infections in both males and females.
2. Symptomatic forms of amoebiasis.
3. Lambliasis and Vincent's angina.
4. Treatment of infections in which anaerobic bacteria have been identified or are suspected as pathogens, particularly Bacteroides fragilis and other species of Bacteroides and including other species for which metronidazole is bactericidal.
5. Prevention of post-operative infections due to anaerobic bacteria.

**CONTRAINDICATIONS:**
Hypersensitivity to metronidazole.
In patients with blood dyscrasias or with active disease of the central nervous system.
The use of metronidazole should be avoided during pregnancy and lactation.

**WARNINGS**
Pseudomembranous colitis has been reported with the use of metronidazole. Alcohol should be avoided during treatment as metronidazole may provoke a disulfiram like reaction. Metronidazole enhances the anticoagulant effect of warfarin.

**DOSAGE AND DIRECTIONS FOR USE:**
Tablets should be swallowed with a half glass of water during or after meals.
Seven days treatment should be satisfactory for most patients. Prolonged treatment can be used if the physician considers it to be necessary. Children over 10 years may be given a suitable proportion of the adult dosage according to body-mass.

**1. Treatment of Anaerobic Infections:**
**Adults and children over 12 years:** 400 mg three times a day.
**Children under 12 years:** 7,5 mg per kg body-mass three times a day.

**2. Prevention of Anaerobic Infections:**
*Gynaecological Surgery:*
**Adults:** 2 g as a single dose followed by 200 mg three times a day until pre-operative withholding of solids and liquids becomes necessary. Medication with 200 mg three times daily should be resumed after the operation and continued for up to seven days.

**3. Vincent's Angina:**
**Adults and children over 12 years:** 200 mg three times a day for three days or 400 mg in the morning and evening for three days.

**4. Treatment of Trichomonas Infections:**
To prevent re-infection to consort should receive a similar course of treatment concurrently.
**Adults and children over 12 years:** either 200 mg three times daily for seven days or, 800 mg in the morning and 1,2 g in the evening for two days.

**5. Treatment of Amoebic Infections:**
**Adults and children over 12 years:** 800 mg three times a day for 5 - 10 days.

**6. Treatment of Lambliasis:**
**Adults and children over 12 years:** 2g once daily for three days.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:**
Side effects include gastro-intestinal discomfort, anorexia, nausea, coated tongue, dry mouth and unpleasant taste, headache, pruritus and skin rash. Other side-effects are vomiting, diarrhoea, weakness, vertigo, ataxia, depression, insomnia, drowsiness, urethral discomfort and darkening of the urine. There may be temporary leucopenia and bone marrow depression. Peripheral neuropathy has been reported in patients on prolonged therapy. Transient fall in blood pressure has been reported. It may therefore be advisable to lower dosage of any antihypertensive drug, which may be given concurrently with **NIDASALL**.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**
See "Side effects"
In recent overdosage gastric lavage is recommended. Further treatment is symptomatic and supportive.

**IDENTIFICATION:**
**400 mg Tablets:** Yellow, biconvexed, scored tablet.
**200 mg Tablets:** White, biconvexed, scored tablet.

**PRESENTATION:**
**400 mg Tablets:** Securitainers containing 100 or 500 tablets.
"Ziploc' patient ready L.D.P.E. plastic bags of different pack sizes (5, 14 or 21 tablets).
**200 mg Tablets:** Securitainers containing 250 tablets.
"Ziploc' patient ready L.D.P.E. plastic bags of different pack sizes (21 or 28 tablets).

**STORAGE INSTRUCTIONS:**
Store at or below 25 $^{0}$C. Protect from light and moisture.
KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**
**400 mg Tablets:** 28/20.2.6/0037
**200 mg Tablets:** 28/20.2.6/0036

**NAME AND BUSINESS ADDRESS OF APPLICANT:**
Innovata Pharmaceuticals (Pty) Ltd.
Crownwood Office Park
100 Northern Parkway
Ormonde
Johannesburg
2091
South Africa

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**
October 2020

**CODE:** PI/NID/002

**SKEDULERINGSTATUS:**
S4

**EIENDOMSNAAM (en doseervorm:**
## NIDASALL 200 (Tablette)
## NIDASALL 400 (Tablette)

**SAMESTELLING:**
**NIDASALL 200:** Elke tablet bevat metronidasool 200mg
**NIDASALL 400:** Elke tablet bevat metronidasool 400mg

**FARMAKOLOGIESE KLASSIFIKASIE:**
A20.2.6. Middels teen protosoe.

**FARMAKOLOGIESE WERKING:**
Metronidasool het 'n antiprotosoe werking en is aktief teen Trichimonas vaginalis, Entamoeba histolytica en Giardia lamblia. Metronidasool is *in-vitro* bakteriedodend vir verskeie anaerobiese organismes.

**INDIKASIES:**
1. Trichomonas infeksies by mans sowel as vrouens.
2. Alie vorme van amebiase.
3. Lambliase en Vincent se angina.
4. Behandeling van infeksies waar anaerobiese bakterie geidentifiseer is of as patogene vermoed word, veral Bacteroides fragilis en ander spesies van Bacteroides asook ander spesies waar metronidasool bakteriedodend is.
5. Voorkoming van na operatiewe infeksie veroorsaak deur anaerobiese bakterieë.

**KONTA-INDIKASIES:**
Oorgevoeligheid vir metronidasool.
By pasiente met bloedsiekte of met 'n aktiewe siektetoestand van die sentrale senuweestelsel.
Die gebruik van metronidasool tydens swangerskap en borsvoeding moet vermy word.

**WAARSKUWINGS:**
Pseudomembraneuse kolitis is al gerapporteer met die gebruik van metronidasool.
Alkohol moet nie gedurende die behandeling met metronidasool geneem word nie aangesien dit aanleiding tot 'n disulfiram-tipe reaksie kan gee.
Metronidasool verhoog die anti-stollende effek van warfarien.

**DOSIS EN GEBRUIKSAANWYSINGS:**
Tablette moet gesluk word met 'n halwe glas water gedurende of na etes.
Behandeling van sewe dae behoort normaalweg vir meeste pasiente voldoende te wees.
Langdurige behandeling kan toegepas word indien die geneesheer dit nodig vind. Kinders bo die ouderdom van 10 jaar kan geskikte hoeveelhede van die volwasse dosis, na gelang van die liggaamsmassa ontvang.

**1. Behandeling van Anaerobiese Infeksies:**
**Volwassenes en kinders ouer as 12 jaar:** 400 mg drie maal per dag.
**Kinders onde12 jaar:** 7,5 mg per kg liggaamsmassa drie maal per dag.

**2. Voorkoming van Anaerobe Infeksies:**
*Ginekologiese Chirurgie.*
**Volwassenes:** 2 g as 'n enkel dosis gevolg deur 200 mg drie maal per dag, totdat vooroperatiewe weerhouding van vaste stowwe en vloeistowwe nodig word.
Behandeling met 200 mg drie maal per dag moet na die operasie hervat word en vir tot sewe dae voortgesit word.

**3. Vincent se Angina:**
**Volwassenes en kinders ouer as 12 jaar:** 200 mg drie maal per dag vir 3 dae of 400 mg soggens en saans vir drie dae.

**4. Behandeling van Trichomonas Infeksies:**
(Om herinfeksie te voorkom moet die konsort gelyktydig 'n soortgelyke kursus van behandeling ontvang).
**Volwassenes en kinders ouer as 12 jaar:** 200 mg drie maal per dag vir sewe dae of 800 mg soggens en 1,2 g saans vir twee dae.

**5. Behandeling van Amebe Infeksies:**
**Volwassenes en kinders ouer as 12 jaar:** 800 mg drie maal per dag vir 5 - 10 dae.

**6. Behandeling van Lambliase:**
**Volwassenes en kinders ouer as 12 jaar:** 2 g een maal per dag vir 3 dae.

**NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**
Newe-effekte is onder andere maagdermongemak, verminderde eetlus, naarheid, aangepakte tong, droe mond en slegtesmaak, hoofpyn, pruritus en veluitslag. Ander newe-effekte wat kan voorkom is vomering, diarree, swakheid, duiseligheid, ataksie, depressie, slaaploosheid, lomerigheid, uretrale ongemak en verdonkering van die urien. Tydelike leukopenie en beenmurgonderdrukking kan soms voorkom. By pasiente wat landurige behandeling ontvang het, is perifere neuropatie al aangemeld. Kortstondige verlaging van die bloeddruk is gerapporteer. Dit is dus gewens om die dosisse van enige antihipertensiewe middels wat saam met **NIDASALL** geneem word, te verlaag.

**BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**
Sien newe-effekte.
Vroegtydige maagspoeling word aanbeveel. Verdere behandeling is simptomaties en ondersteunend.

**IDENTIFIKASIE:**
**400 mg Tablette:** Geel, bikonvekse, gekeepte tablet.
**200 mg Tablette:** Wit, bikonvekse, gekeepte tablet.

**AANBIEDING:**
**400 mg Tablette:** Sekuritainers wat 100 of 500 tablette bevat.
L.D.P.E. plastiese 'ziploc' pasiënt gereed pakkette van verskillende pakgrottes (5, 14 of 21 tablette)
**200 mg Tablette:** Sekuritainers bevat 200 tablette.
L.D.P.E. plastiese 'ziploc' pasiënt gereed pakkette van verskillende pakgrottes (21 of 28 tablette)

**BERGINGSAANWYSINGS:**
Berg benede 25 $^{0}$C. Beskerm teen lig en vog.
HOU BUITE DIE BEREIK VAN KINDERS.

**REGISTRASIENOMMERS:**
**400 mg Tablette:** 28/20.2.6/0037
**200 mg Tablette:** 28/20.2.6/0036

**NAAM EN BESIGHEIDSADRES VAN DIE APPLIKANT:**
Innovata Pharmaceuticals (Edms) Bpk.
Crownwood Office Park
Northern Parkway 100
Ormonde
Johannesburg
2091
Suid-Afrika

27/01/2022

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:**
Ocktober 2020

**KODE:** PI/NID/002

JET PRINTERS cc

# PRINTERS PROOF

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|---|---|
| **File Number** | |
| Repro Ticket | |
| **Customer** | |
| Product | NIDASALL 200 (Tablets)<br>NIDASALL 400 (Tablets) |
| Code | PI/NID/002 |
| Flat Size | 330 (L) X 100 (W) |
| Folded Size | |
| Pharma Code | |
| **Colours** | BLACK |
| **Proof No** | 2 |
| Date | 24/01/2022 |
| Operator | |
| Proof Reader | |

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