SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
Bio-Metronidazole 200 (Tablets)
Bio-Metronidazole 400 (Tablets)

COMPOSITION:
Each Bio-Metronidazole 200 tablet contains 200 mg metronidazole
Each Bio-Metronidazole 400 tablet contains 400 mg metronidazole
Excipients: Colloidal silicon dioxide, lactose, magnesium stearate, maize starch, pregelatinised starch, povidone.
Bio-Metronidazole 200 tablet contains 200 mg lactose per tablet.
Bio-Metronidazole 400 tablet contains 150 mg lactose per tablet.
CONTAINS SUGAR

PHARMACOLOGICAL CLASSIFICATION:
A 20.2.6 Medicines against protozoa

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Metronidazole is active *in vitro* against a wide variety of anaerobic protozoal parasites and anaerobic bacteria. It has antiprotozoal activity against *Trichomonas vaginalis* and other protozoa, including *Entamoeba histolytica* and *Giardia lamblia*.
Metronidazole has bactericidal activity against obligate anaerobic bacteria (Gram positive and negative) and bacilli or cocci. It does not affect the acidophilic flora of the vagina. It is not effective against aerobic, facultative anaerobic bacteria as well as Candida species.
Pharmacokinetic properties
Metronidazole is completely absorbed after oral administration. The half-life of metronidazole in plasma is about 8 hours with less than 20 % of metronidazole bound to plasma proteins.
After an oral dose over 75 % of metronidazole is eliminated in the urine largely as metabolites; about 10 % is recovered as unchanged metronidazole. The liver is the main site of metabolism. Metronidazole crosses the blood - brain barrier.

INDICATIONS:
Indicated in the treatment of:
- Urogenital trichomoniasis
- Non-specific vaginitis
- All forms of amoebiasis
- Acute ulcerative gingivitis (Vincent's angina)
- Giardiasis
- Acute pericoronitis

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, such as fusobacteria, clostridia, eubacteria and anaerobic streptococci.
Bio-Metronidazole has been used successfully for anaerobic infections in the following conditions: pelvic inflammatory disease and postoperative wound infections. Combined therapy is often indicated as there are usually mixed infections.
Prevention of post-operative infections due to anaerobic bacteria, particularly species of bacteroides and anaerobic streptococci. Given alone before or after gynaecological surgery or appendectomy; or given together with appropriate antibacterial agents before or after colonic surgery.
Treatment of Helicobacter pylori-associated gastritis and duodenal ulcer. Bio-Metronidazole is used in combination with other appropriate therapy.

CONTRAINDICATIONS:
The use of Bio-Metronidazole should be avoided during pregnancy and breastfeeding (see PREGNANCY AND LACTATION), and in patients with blood dyscrasias or central nervous system diseases.
Contraindicated in patients hypersensitive to metronidazole, other imidazoles or any of the excipients.

WARNINGS AND SPECIAL PRECAUTIONS:
When given in conjunction with alcohol, Bio-Metronidazole may provoke a disulfiram-like reaction (see INTERACTIONS).
Pseudomembranous colitis has been reported following the use of Bio-Metronidazole.
Special Precautions
Transient falls in blood pressure have been reported with the use of Bio-Metronidazole. It may therefore be advisable to lower the dosage of antihypertensive medicine which may be given concurrently with Bio-Metronidazole.
When repeat courses are required, leukocyte counts should be performed before, during and after each course of treatment. In patients with blood dyscrasias or with active or chronic disease of the central and peripheral nervous system Bio-Metronidazole should be used with great care.
All patients receiving treatment with Bio-Metronidazole for more than 10 days should be closely monitored and treatment should be discontinued if signs of peripheral neuropathy or central nervous system toxicity develop.
In patients with severe liver disease the dose of Bio-Metronidazole should be reduced.
As plasma levels of busulfan may be increased significantly by the co-administration with Bio-Metronidazole, it may lead to severe busulfan toxicity and even death (refer to INTERACTIONS).
Due to the anti-treponemal activity of Bio-Metronidazole it may mask the immunological response seen in untreated early syphilis and contacts of syphilis treated with Bio-Metronidazole should probably be screened for an additional 4 to 8 weeks.
Effects on the ability to drive and use machines:
Bio-Metronidazole may cause confusion, dizziness, hallucinations, convulsions or transient visual disorders and patients should be warned regarding this and advised not to drive or operate machinery if these symptoms occur.
Lactose
Bio-Metronidazole contains small amount of lactose. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

INTERACTIONS:
Bio-Metronidazole enhances the anti-coagulant effect of warfarin.
Bio-Metronidazole used concomitantly with alcohol may provoke a disulfiram-like reaction in some individuals. This reaction has occurred following the use of pharmaceutical preparations formulated with alcohol, including injections, as well as after consuming alcohol. The concomitant use of Bio-Metronidazole and disulfiram has been associated with acute psychoses or confusion.
Bio-Metronidazole may impair the clearance of phenytoin, lithium and fluorouracil.
Phenytoin might accelerate the metabolism of Bio-Metronidazole.
Phenobarbitone administered concomitantly with Bio-Metronidazole causes decreased plasma concentrations of Bio-Metronidazole and thus leading to a reduction in the effectiveness of Bio-Metronidazole.
Cimetidine may increase plasma concentrations of Bio-Metronidazole and might increase the risk of neurological side effects.
The risk of elevation of serum levels of cyclosporine might be increased by Bio-Metronidazole.
The co-administration with busulfan may increase plasma levels of busulfan so significantly that it might lead to severe busulfan toxicity and death (refer to WARNINGS AND SPECIAL PRECAUTIONS).

PREGNANCY AND LACTATION:
The safety of Bio-Metronidazole has not been established in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE:
Administration
Tablets should be swallowed without chewing, with adequate water, preferably during or after meals.

	DURATION OF DOSAGE IN DAYS	ADULTS	CHILDREN 7 TO 10 YEARS
UROGENITAL TRICHOMONIASIS	1	2 g as a single dose	
Where re-infection is likely, in adults the consort should receive a similar course of treatment concurrently.	7	200 mg three times daily or 400 mg twice daily	100 mg three times daily
	2	800 mg in the morning and 1,2 g in the evening	
NON-SPECIFIC VAGINITIS	7	400 mg twice daily	7
	OR 1	2 g as a single dose	OR 1
AMOEBIASIS a) Invasive intestinal disease in susceptible subjects.	5	800 mg three times daily	400 mg three times daily
AMOEBIASIS b) Intestinal disease in less susceptible subjects and "chronic amoebic hepatitis".	5 to 10	400 mg three times daily	200 mg three times daily
AMOEBIASIS c) Amoebic liver abscess, also other forms extra-intestinal amoebiasis	5	400 mg three times daily	200 mg three times daily
AMOEBIASIS d) Symptomless cyst passers	5 to 10	400 to 800 mg three times daily	200 to 400 mg three times daily
GIARDIASIS A second course of treatment may be necessary for some patients two weeks after the end of the first course.			
ACUTE ULCERATIVE GINGIVITIS	3	200 mg three times daily	100 mg three times daily
ACUTE PERICORONITIS	3 to 7	200 mg three times daily	

Anaerobic Infections
a) Treatment:
Bio-Metronidazole may be given alone or concurrently with other bacteriologically appropriate antibacterial agents. They should be given for 7 days or longer depending on clinical and bacteriological assessments of the patient's condition.
Adults: Initially, 800 mg followed by 400 mg by mouth every 8 hours.
Children: 7,5 mg/kg body mass by mouth every 8 hours.
b) Prevention:
Adults: Administered in doses similar to those used for the treatment of established infection. 400 mg may be given every 8 hours in the 24 hours before surgery followed postoperatively by intravenous or rectal administration until oral therapy is possible.
Children: as for treatment (a).
Treatment of Helicobacter pylori-associated gastritis and duodenal ulcer:
Bio-Metronidazole 200 mg – 5 times a day for 14 days in combination with other appropriate therapy.

SIDE EFFECTS :
Gastrointestinal disorders
Frequent: Gastrointestinal discomfort, anorexia, nausea and unpleasant taste; vomiting and headache may accompany the nausea. Diarrhoea, dry mouth, coated tongue, oral mucositis and stomatitis may also occur.
Less frequent: Antibiotic-associated colitis, pancreatitis, pseudomembranous colitis associated with the use of Bio-Metronidazole.
Nervous system disorders
Frequent: Vertigo (dizziness or lightheadedness)
Less frequent: Peripheral neuropathy (numbness, tingling, pain, or weakness in hands or feet) has been reported with high doses or in patients on prolonged treatment; seizures – usually with high doses. Reports of encephalopathy (e.g. confusion) and subacute cerebellar syndrome (e.g. ataxia dysarthria, gait impairment, nystagmus and tremor), which may resolve with discontinuation of Bio- Metronidazole.
Frequency unknown: Psychotic disorders including confusion, irritability and hallucinations. Weakness, drowsiness, insomnia, and changes in mood or mental state such as depression or confusion.
Blood and lymphatic system disorders
Less frequent: Temporary moderate leucopenia, thrombocytopenia, agranulocytosis, neutropenia.
Skin and subcutaneous tissue disorders
Less frequent: Pruritus, skin rash, fever, angioedema, flushing, urticaria, anaphylaxis. Pustular eruptions may occur. Mild erythematous eruptions with fleeting joint pains resembling serum sickness.
Musculoskeletal, connective tissue and bone disorders
Frequency unknown: Myalgia and arthralgia.
Eye disorders
Frequency unknown: Transient vision disorders such as diplopia and myopia.
Respiratory, thoracic and mediastinal disorders
Frequency unknown: Nasal congestion.
Hepato-biliary disorders
Less frequent: Raised liver enzyme values, reversible abnormal liver function and cholestatic hepatitis.
Renal and urinary disorders
Less frequent: Urethral discomfort, and darkening of the urine

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Refer to SIDE EFFECTS. Treatment is symptomatic and supportive, but early gastric lavage is recommended.

IDENTIFICATION:
Bio-Metronidazole 200:
A white biconvex tablet, indented MZL 200 and a breakline on one side.
Bio-Metronidazole 400:
A white biconvex tablet, indented MZL 400 and a breakline on one side.

PRESENTATION:
Bio-Metronidazole 200:
Securitainers with 250 tablets or Patient Ready Pack (LDPE Bag) with 21, 28 tablets.
7 tablets per blister strip and 1, 2, or 3 blisters per outer carton.
Bio-Metronidazole 400:
Securitainers with 21, 100 and 500 tablets or Patient Ready Pack (LDPE Bag) with 5, 14, 21 tablets.
7 tablets per blister strip and 1, 2 or 3 blisters per outer carton.
HDPE Container with cap, containing 100 and 500 tablets.

STORAGE INSTRUCTIONS:
Store at or below 25 °C and protect from light.
Do not remove the blisters from the outer carton until required for use.
KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER:
BIO-METRONIDAZOLE 200: V/20.2.6/370
BIO-METRONIDAZOLE 400: V/20.2.6/371

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
South Africa

DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date of Registration: 30 November 1988
Date of latest revision of the text as approved by Council: 02 March 2012
Date of notification with regard to amended Reg. 9 and 10: 02 February 2015

Bio-Metronidazole 400	
Namibia: Reg. No.: 11/20.2.6/0184	NS2

SKEDULERINGSTATUS:
S4

EIENDOMSNAAM EN DOSEERVORM:
Bio-Metronidazole 200 (Tablette)
Bio-Metronidazole 400 (Tablette)

SAMESTELLING:
Elke Bio-Metronidazole 200 tablet bevat 200 mg metronidasool.
Elke Bio-Metronidazole 400 tablet bevat 400 mg metronidasool.
Onaktiewe bestanddele: kolloïdale silikoon dioksied, laktose, magnesiumstearaat, mieliestysel, pregegelatiniseerde stysel, povidoon.
Bio-Metronidazole 200 tablette bevat 200 mg laktose per tablet.
Bio-Metronidazole 400 tablette bevat 150 mg laktose per tablet.
BEVAT SUIKER

FARMAKOLOGIESE KLASSIFIKASIE:
A 20.2.6 Medisyne teen protosoa

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Metronidasool is *in vitro* aktief teen 'n wye verskeidenheid anaërobiese protosoïese parasiete en anaerobiese bakterieë. Dit het antiprotosoïese aktiwiteit teen *Trichomonas vaginalis* en ander protosoa, insluitend *Entamoeba histolytica* en *Giardia lamblia*.
Metronidasool het kiemdodende aktiwiteit teenoor obligatoriese anaërobiese bakterieë (Gram positief en negatief) en basille of kokke. Dit affekteer glad nie die asidofiliese flora in die vagina nie. Dit is ook nie effektief teen aërobiese, fakultatiewe anaërobiese bakterieë sowel as die Candida spesie nie.
Farmakokinetiese eienskappe
Metronidasool word heeltemaal geabsorbeer na orale toediening. Met minder as 20 % van die metronidasool wat aan die plasma proteïen bind, is die halfleeftyd van metronidasool in plasma ongeveer 8 ure. Na 'n orale dosis word meer as 75 % van die metronidasool hoofsaaklik as metaboliete in die uriene uitgeskei; omtrent 10 % word as onveranderde metronidasool uitgeskei. Metabolisme vind hoofsaaklik in die lewer plaas. Metronidasool is in staat om oor die bloedbreinskans te beweeg.

INDIKASIES:
Vir die behandeling van:
- Urogenitale trigomoniase
- Nie-spesifieke vaginitis
- Alle vorms van amebiase
- Akute ulseratiewe gingivitis (Vincent se gingivitis)
- Giardiase
- Akute perikoronitis

Behandeling van infeksies waar anaerobe bakterieë as patogene geïdentifiseer of vermoed word, veral Bacteroides fragilis en ander bakteroïede spesies, insluitend ander spesies waarvoor metronidasool bakteriosidies is, soos bv. fusobakterieë, clostridia, eubakterieë en anaerobe streptokokke. Bio-Metronidazole is met sukses gebruik vir anaerobe infeksies in die volgende toestande: pelviese inflammatoriese siekte en postoperatiewe wondinfeksies. Gekombineerde terapie word dikwels aangedui omdat hierdie toestande gewoonlik met gemengde infeksies geassosieer word.
Voorkoming van postoperatiewe infeksies a.g.v. anaërobe bakterieë, spesifiek spesies van bakteroïede en anaërobiese streptokokke. Toediening voor of na ginekologiese chirurgie of appendektomie; of as toegedien word saam met geskikte antibakteriële middels voor of na kolonchirurgie.
Behandeling van Helicobacter pylori-geassosieerde gastritis en duodenale ulkus. Bio-Metronidazole word in kombinasie met ander toepaslike behandeling gebruik vir hierdie infeksies.

KONTRAINDIKASIES:
Die gebruik van Bio-Metronidazole moet vermy word gedurende swangerskap en borsvoeding (sien SWANGERSKAP EN BORSVOEDING), asook in pasiënte met bloed diskrasie of sentrale senustelsel siektes. Bio-Metronidazole is teenagedui in pasiënte wat hipersensitiwiteit teenoor metronidasool en ander imidasole of enige van die onaktiewe bestanddele toon.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Wanneer Bio-Metronidazole saam met alkohol geneem word, kan dit 'n disulfiram-agtige reaksie laat ontstaan (sien INTERAKSIES).
Pseudomembraneuse kolitis nadat Bio-Metronidazole gebruik is, is al aangemeld.
Spesiale Voorsorgmaatreëls
Kortstondige dalings in bloeddruk is aangemeld tydens die gebruik van Bio-Metronidazole. Dit mag dus raadsaam wees om die dosis van antihipertensie medisyne, wat saam met Bio-Metronidazole gebruik word, te verlaag.
Leukosiet tellings moet uitgevoer word voor, tydens en na elke behandelingskursus voltooi is, alvorens besluit word of 'n kursusherhaling nodig is.
Bio-Metronidazole moet met uiterse omsigtigheid gebruik word by pasiënte met bloeddiskrasieë of met aktiewe chroniese siektes van die sentrale en perifere senustelsel.
Alle pasiënte wat Bio-Metronidazole vir langer as 10 dae ontvang, moet gemonitor word en indien tekens van perifere neuropatie of sentrale senustelsel toksisiteit ontwikkel, moet behandeling gestaak word.
Dosisse van Bio-Metronidazole moet verminder word in pasiënte met erge lewersiekte.
Aangesien plasmavlakke van bisulfan noemenswaardig verhoog kan word indien dit gelyktydig met Bio-Metronidazole toegedien word, kan dit tot erge bisulfantoksisiteit en die dood lei (sien INTERAKSIES).
As gevolg van die antitreponemale aktiwiteit van Bio-Metronidazole mag die immunologiese reaksie wat in onbehandelde sifilis gesien word, versteek word. Sifiliskontakte wat met Bio-Metronidazole behandel word, behoort waarskynlik vir 'n addisionele 4 – 8 weke gemonitor word.
Uitwerking op die vermoë om 'n voertuig te bestuur en masjinerie te hanteer:
Bio-Metronidazole kan verwarring, duiseligheid, hallusinasies, konvulsies en verbygaande visuele afwykings veroorsaak, pasiënte moet dus hieroor gewaarsku word, en adviseer word om nie voertuie te bestuur of masjinerie the hanteer indien hierdie simptome voorkom nie.
Laktose
Bio-Metronidazole bevat 'n klein hoeveelheid laktose. Pasiënte met seldsame oorerflike probleme van galaktose onverdraagsaamheid, erge laktase tekort or glukose-galaktose wanabsorpsie moet dus nie hierdie medisyne gebruik nie.

INTERAKSIES:
Bio-Metronidazole versterk die antistol werking van warfarien.
Wanneer Bio-Metronidazole saam met alkohol geneem word, mag dit 'n disulfram-agtige reaksie in sommige individue veroorsaak. Hierdie reaksie het voorgekom na die gebruik van farmaseutiese preparate wat alkohol bevat, insluitend inspuitings, asook nadat pasiënte alkohol gedrink het.
Die gelyktydige gebruik van Bio-Metronidazole en disulfiram word geassosieer met akute psigose of verwarring.
Bio-Metronidazole kan die opruiming van fenitoïen, litium en fluorurasiel inkort.
Fenitoïen kan die metabolisme van Bio-Metronidazole versnel.
Plasmakonsentrasies van Bio-Metronidazole word verlaag deur die gelyktydige toediening van fenobarbitoon, dit het tot gevolg dat die effektiwiteit van Bio-Metronidazole verlaag word.
Simetidien kan plasmakonsentrasies van Bio-Metronidazole verhoog en kan die risiko van neurologiese newe effekte verhoog.
Bio-Metronidazole kan die risiko van 'n styging in siklosporienvlakke verhoog.
Die toediening van Bio-Metronidazole tesame met bisulfan, kan die plasmavlakke van bisulfan so noemenswaardig verhoog, dat dit kan lei tot erge bisulfan-toksisiteit en die dood (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS)

SWANGERSKAP EN BORSVOEDING:
Veiligheid van die gebruik van Bio-Metronidazole tydens swangerskap en borsvoeding is nie vasgestel nie.

DOSIS EN GEBRUIKSAANWYSINGS:
Toediening
Die tablette moet gesluk word sonder om dit te kou, met genoeg water, verkieslik gedurende of na maaltye.

	DUUR VAN DOSIS IN DAE	VOLWASSENES	KINDERS 7 TOT 10 JAAR
UROGENITALE TRIGOMONIASE Waar herinfeksie in volwassenes waarskynlik is, moet die geslagsmaat gelyktydig 'n soortgelyke behandelingskursus ontvang	1	2 g as 'n enkeldosis	
	7	200 mg drie maal per dag of 400 mg twee maal per dag	100 mg drie maal per dag
	2	800 mg in die oggend en 1,2 g in die aand	
NIE-SPESIFIEKE VAGINITIS	7	400 mg twee maal per dag	7
	OF 1	2 g as 'n enkeldosis	OF 1
AMEBIASE a) Indringende intestinale siekte in vatbare persone.	5	800 mg drie maal per dag	400 mg drie maal per dag
AMEBIASE b) Intestinale siekte in minder vatbare persone en "chroniese amebiese hepatitis".	5 tot 10	400 mg drie maal per dag	200 mg drie maal per dag
AMEBIASE c) Amebiese lewerabses, ook ander amebiase.	5	400 mg drie maal per dag	200 mg drie maal per dag
AMEBIASE d) Simptoomlose sist-uitskeiers	5 tot 10	400 tot 800 mg drie maal per dag	200 tot 400 mg drie maal per dag
GIARDIASE 'n Tweede kursus behandeling mag nodig wees vir sommige pasiënte twee weke na die einde van die eerste kursus.			
AKUTE ULSERATIEWE GINGIVITIS	3	200 mg drie maal per dag	100 mg drie maal per dag
AKUTE PERIKORONITIS	3 to 7	200 mg drie maal per dag	

Anaerobiese infeksies
a) Behandeling:
Bio-Metronidazole kan alleen of saam met ander bakteriologies toepaslike antibakteriële middels toegedien word. Dit moet vir 7 dae of langer toegedien word, afhangende van die kliniese en bakteriologiese bepaling van die pasiënt se toestand.
Volwassenes: Aanvanklik, 800 mg gevolg deur 400 mg mondelings, elke 8 uur.
Kinders: 7,5 mg/kg liggaamsmassa mondelings elke 8 uur.
b) Voorkoming:
Volwassenes: Dien toe in dosisse wat soortgelyk is aan die wat in gevestigde infeksie gebruik word, 400 mg kan elke 8 uur tydens die 24 uur voor chirurgie gegee word, wat dan postoperatief deur intraveneuse of rektale toediening gevolg word, totdat mondelingse behandeling weer moontlik is.
Kinders: behandeling soos in (a).
Behandeling van Helicobacter pylori-geassosieerde gastritis duodenale ulkus:
Bio-Metronidazole 200 mg, 5 maal per dag, vir 14 dae in kombinasie met ander geskikte behandelings.

NEWE EFFEKTE:
Spysverteringstelsel afwykings
Dikwels: Gastrointestinale ongemak, anoreksie, naarheid en ongeurige smaaksensasies; braking en hoofpyn kan die naarheid vergesel. Diarree, droeë mond, aanpaksel op tong, orale mukositis en stomatitis kan ook voorkom.
Minder dikwels: Antibiotika-geassosieerde kolitis, pankreatitis, pseudomembraneuse kolitis geassosieer met die gebruik van Bio-Metronidazole.
Senuweestelsel afwykings
Dikwels: Vertigo (duiseligheid of lighoofdigheid)
Minder dikwels: Perifere neuropatie (gevoelloosheid, prikkeling, pyn of swakheid in hande en voete) is aangemeld met hoë dosisse of in pasiënte op langdurige behandeling; stuipe – gewoonlik met hoë dosisse. Melding van ensefalopatie (bv. verwarring) en subakute serebellêre sindroom (bv. ataksie disartrie, inkorting van die manier van loop, nistagmus en bewerasie) wat kan opklaar met staking van die gebruik van Bio-Metronodazole.
Gebeurlikheid onbekend: Psigotiese versteurings insluitende verwarring, geïrriteerdheid en hallusinasies. Swakheid, lomerigheid, slaaploosheid en veranderings in luim of geestestoestand soos depressie of verwarring is aangemeld.
Bloed- en limfstelsel afwykings
Minder dikwels: Tydelike matige leukopenie, trombositopenie, agranulositose, neutropenie.
Vel- en subkutaneweefsel afwykings
Minder dikwels: Pruritus, veluitslag, koors, angioëdeem, blosing, urtikarie, anafilakse. Pustulêre erupsies kan voorkom. Matige eritemateuse erupsies met vlietende gewrigspyn wat ooreenkom met serumsiekte.
Muskuloskeletale, bindweefsel- en beenafwykings
Gebeurlikheid onbekend: Mialgie and artralgie.
Oogafwykings
Gebeurlikheid onbekend: Verbygaande sigsteurnisse soos diplopie en miopie.
Respiratoriese, torakale en mediastinale afwykings
Gebeurlikheid onbekend: Neuskongestie.
Hepato-bilière afwykings
Minder dikwels: Verhoogde lewerensiemwaardes, omkeerbare abnormale lewerfunksie en cholestatiese hepatitis.
Renale en urinêre afwykings
Minder dikwels: Uretrale ongemak en donkerkleurige uriene.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Verwys na NEWE EFFEKTE. Behandeling is simptomaties en ondersteunend, maar vroeë maagspoeling word aanbeveel.

IDENTIFIKASIE:
Bio-Metronidazole 200:
'n Wit, bikonvekse tablet waarop MZL 200 gegrafeer is, en 'n breeklyn op die een kant.
Bio-Metronidazole 400:
'n Wit, bikonvekse tablet waarop MZL 400 gegrafeer is, en 'n breeklyn op die een kant.

AANBIEDING
Bio-Metronidazole 200:
Veiligheidshouers met 250 tablette, of 'n voorafgepakte sakkie (LDPE sakkie) met 21 of 28 tablette.
7 tablette per stulpstrook en 1, 2 of 3 stulpstroke per kartonhouer.
Bio-Metronidazole 400:
Veiligheidshouers met 21, 100 en 500 tablette of 'n voorafgepakte sakkie (LDPE sakkie) met 5, 14 of 21 tablette.
7 tablette per stulpstrook en 1, 2 of 3 stulpstroke per kartonhouer.
HDPE houer met deksel, bevattend 100 en 500 tablette.

BERGINGSINSTRUKSIES:
Bewaar by of benede 25 °C en beskerm teen lig.
Bewaar die stulpstroke in die buitenste kartonhouer tot benodig vir gebruik.
HOU BUITE DIE BEREIK VAN KINDERS

REGISTRASIENOMMER:
BIO-METRONIDAZOLE 200: V/20.2.6/370
BIO-METRONIDAZOLE 400: V/20.2.6/371

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
Biotech Laboratories (Edms) Bpk.
Grondvloër, Block K West, Central Park,
400 16de Weg, Randjespark, Midrand, 1685,
Suid Afrika

DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET:
Datum van registrasie: 30 November 1988
Datum van nuutste hersiening van die teks soos goedgekeur deur die Raad: 2 Maart 2012
Datum van kennisgewing met betrekking tot wysig Reg. 9 en 10: 06 Februarie 2015

Bio-Metronidazole 400	
Namibië: Reg. Nr.: 11/20.2.6/0184	NS2