SCHEDULING STATUS:
S4

PROPRIETARY NAME AND DOSAGE FORM:
BIO METRONIDAZOLE IV (Intravenous Infusion)

COMPOSITION:
Each 100 ml solution contains 500 mg metronidazole.
Excipients:Sodium chloride, dibasic sodium phosphate (anhydrous), citric acid monohydrate, and water for injection.

PHARMACOLOGICAL CLASSIFICATION:
A. 20.2 Other than antibiotics.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Metronidazole is a pro-drug; it requires reductive activation of the nitro group by susceptible organisms. The parent compound penetrates the cell membrane unchanged, but once inside the cell the nitro group is reduced by the reduction-oxidation conditions prevalent in the anaerobic cell. Reduced metronidazole, which is cytotoxic but short-lived, interacts with DNA to cause a loss of helical structure, strand breakage, and resultant inhibition of nucleic acid synthesis and cell death. Metronidazole has bactericidal activity against anaerobic bacteria. Metronidazole has antiprotozoal activity against Trichomonas vaginalis and other protozoa, including Entamoeba histolytica and Giardia lamblia. Metronidazole has no effect on Candida species and it does not affect the acidophilic flora of the vagina.
Metronidazole does not impede the activity of antibacterial agents which are active against a variety of aerobes and facultative anaerobes. Metronidazole manifests antibacterial activity against all anaerobic cocci and both anaerobic gram-negative bacilli, including Bacteroides species, and anaerobic spore-forming gram-positive bacilli.
Pharmacokinetics properties
At recommended intravenous doses, peak steady-state serum concentrations are approximately 25 µg/ml.
Metronidazole is distributed to the bone, liver and liver abscesses, lungs, vaginal secretions, seminal fluids, bile, saliva and breast milk. It also crosses the placenta and the blood brain barrier.
The half-life in plasma is about 8 hours, and its volume of distribution is approximately that of total body water. Less than 20 % of the medicine is bound to plasma proteins. Therapeutic concentrations also are achieved in cerebrospinal fluid. The liver is the main site of metabolism, and this accounts for over 50 % of the systemic clearance of metronidazole. The hydroxy metabolite has a half-life of 12 hours. About 60 – 80 % is excreted in urine via the kidneys (20 % of this amount is excreted unchanged), and about 6 – 15 % as inactive metabolites in faeces.
Metronidazole and its metabolites are significantly removed by haemodialysis, but insignificantly by peritoneal dialysis.

INDICATIONS:
For the treatment of infection in which anaerobic bacteria have been identified or are suspected as pathogens, particularly Bacteroides fragilis and other species of bacteroides, for which BIO METRONIDAZOLE IV is bactericidal, such as streptococci, fusobacteria, eubacteria and clostridia, when the oral route is unsuitable.
a) BIO METRONIDAZOLE IV is used for anaerobic infections in the following indications:
- postoperative wound infections and
- pelvic inflammatory disease.

As these are usually mixed infections, combination therapy is often indicated.
b) BIO METRONIDAZOLE IV is also used for the prevention of postoperative infections due to anaerobic bacteria:
Given before and after:
(i) Appendicectomy,
(ii) Gynaecological surgery and
(iii) Colonic surgery.

CONTRAINDICATIONS:
In patients who are hypersensitive to metronidazole, other imidazoles, or any of the excipients of BIO METRONIDAZOLE IV.
Pregnancy and lactation.

WARNINGS AND SPECIAL PRECAUTIONS:
Drinking of alcohol or concomitant administration of pharmaceutical preparations formulated with alcohol, including injections, during BIO METRONIDAZOLE IV therapy, and for at least one day after cessation of therapy may provoke disulfiram-like reactions such as abdominal cramps, nausea, vomiting, headache or flushing, in some patients. Concomitant use of BIO METRONIDAZOLE IV and disulfiram may increase the side effects. Acute psychoses and confusional states have been reported when BIO METRONIDAZOLE IV was used concomitantly with disulfiram in alcoholic patients. Pseudomembranous colitis has been reported with the use of BIO METRONIDAZOLE IV. Peripheral neuropathy, transient epileptiform seizures, and leucopoenia have sometimes been associated with prolonged or intensive treatment with BIO METRONIDAZOLE IV. Clinical and laboratory monitoring is advised in patients receiving BIO METRONIDAZOLE IV for more than 10 days, treatment should be discontinued if signs of peripheral neuropathy or nervous system toxicity develop. Doses should be reduced in patients with severe hepatic impairment.
BIO METRONIDAZOLE IV should be used with great care in patients with blood dyscrasias or with active or chronic disease of the central and peripheral nervous system. BIO METRONIDAZOLE IV may mask the immunological response seen in untreated early syphilis, due to its anti-treponemal activity. Patients suspected of having syphilis while receiving BIO METRONIDAZOLE IV should probably be screened for an additional 4 to 8 weeks.
Effects on the ability to drive and use machines:
BIO METRONIDAZOLE IV has the potential to cause confusion, dizziness, unsteadiness, convulsions or visual disorders. When these symptoms occur patients should be advised not to drive or operate machinery.

INTERACTIONS:
BIO METRONIDAZOLE IV is reported to impair the metabolism or excretion of several medicines including warfarin, phenytoin, lithium and fluorouracil, with the consequent potential for an increased incidence of adverse effects. There is some evidence that phenytoin might accelerate the metabolism of BIO METRONIDAZOLE IV. Plasma concentrations of BIO METRONIDAZOLE IV are decreased by the concomitant administration of phenobarbital, with a consequent reduction in the effectiveness of BIO METRONIDAZOLE IV. Cimetidine has increased plasma concentrations of BIO METRONIDAZOLE IV and might increase the risk of neurological side effects.
BIO METRONIDAZOLE IV might increase the risk of elevation of the serum levels of cyclosporine. When taken with alcohol, BIO METRONIDAZOLE IV may provoke disulfiram-like reactions as well as acute psychoses or confusion (see WARNINGS AND SPECIAL PRECAUTIONS). Lithium concentrations may increase (when BIO METRONIDAZOLE IV therapy is introduced) and thus serum lithium and serum creatinine levels should be monitored several days after beginning treatment to detect lithium intoxication.

PREGNANCY AND LACTATION:
Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:
Treatment of anaerobic infections:
Adults and adolescents (over 12 years) dose:
100 ml (500 mg/100 ml) by intravenous infusion every 8 hours. The injection should be infused intravenously at the rate of 5 ml per minute, but may be administered alone or concurrently (but separately) with other bacteriologically appropriate antibacterial agents in parental dosage forms.
Children under 12 years:
As for adults, but the single intravenous dose is based on 1,5 ml (7,5 mg BIO METRONIDAZOLE IV)/kg body mass and the oral dose of 7,5 mg/kg body mass.
Prevention:
Adults and adolescents (over 12 years) dose:
100 ml (500 mg/100 ml) by intravenous infusion immediately before, during or after operation, followed by the same dose 8 hourly until oral medication can be given.
Children under 12 years:
As for adults but the single intravenous dose is based on 1,5 ml (7,5 mg BIO METRONIDAZOLE IV)/kg body mass and the oral dose on 7,5 mg/kg body mass.
BIO METRONIDAZOLE IV injection compatibilities:
BIO METRONIDAZOLE IV injection is compatible with the following injections:
Sodium chloride injection 0,9 % m/v (normal saline injection)
Dextrose 5 % m/v injection
Sterile water for injection
Bacteriostatic water for injection
Bacteriostatic sodium chloride 0,9 %
Ringer's injection, lactated

SIDE EFFECTS:
Nervous system disorders
Frequent: Central Nervous System (CNS) effects such as dizziness or light-headedness; headache.
Less frequent: Peripheral neuropathy, usually presenting as numbness or tingling in the extremities, and seizures are serious adverse effects associated with high doses or prolonged treatment. CNS toxicity such as ataxia, clumsiness or unsteadiness; encephalopathy – mood or mental changes such as depression or confusion and seizures/convulsions.
Frequency not known: Weakness. Psychotic disorders including confusion, irritability and hallucinations; drowsiness, insomnia.
General disorders and administration site conditions
Less frequent: Change in taste sensation; dryness of mouth; unpleasant or sharp metallic taste; thrombophlebitis manifesting as pain, tenderness, redness or swelling at site of injection.
Immune system disorders
Less frequent: Hypersensitivity manifesting as skin rash, fever, angioedema, hives, flushing, or urticaria, pruritus, anaphylaxis.
Frequency not known: Mild erythematous eruptions with fleeting joint pains resembling serum sickness may occur.
Blood disorders
Less frequent: Leucopenia (sore throat and fever); thrombocytopenia.
Frequency not known: Agranulocytosis, neutropenia.
Endocrine disorders
Less frequent: Pancreatitis.
Renal and urinary disorders
Less frequent: Urinary tract effects such as dysuria, increased urinary frequency, frequent or painful urination; inability to control urine flow; sense of pelvic pressure; dark urine.
Infections and infestations
Less frequent: Vaginal candidiasis
Gastro-intestinal disorders
Frequent: Gastrointestinal disturbances
Frequency not known: Antibiotic-associated colitis, pseudomembranous colitis. Nausea, loss of appetite and taste disorders; nausea is sometimes accompanied by headache, anorexia and vomiting. Diarrhoea, dry mouth, a furred tongue and stomatitis may occur.
Skin and subcutaneous tissue disorders
*Frequency not known:*Skin rashes. Pustular eruptions may occur.
Musculoskeletal, connective tissue and bone disorders
*Frequency not known:*Myalgia and arthralgia.
Eye disorders
Frequency not known: Transient vision disorders such as diplopia and myopia have been reported.
Hepato-biliary disorders
Frequency not known: Raised liver enzyme values have occasionally been reported. Cases of reversible abnormal liver function and cholestatic hepatitis have been reported.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
(See SIDE EFFECTS).
There is no specific antidote. Treatment is symptomatic and supportive.

IDENTIFICATION:
A clear, colourless to pale yellow solution. The solution is sterile and free from particulate matter.

PRESENTATION:
BIO METRONIDAZOLE IV is packed in a 100 ml transparent white LDPE bottle.
Each bottle is wrapped with a transparent clear polypropylene wrapper.

STORAGE INSTRUCTIONS:
Store at or below 30 °C. Do not refrigerate.
For single use only. Discard any remaining contents after use.
Protect form light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
42/20.2/0567

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
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DATE OF PUBLICATION OF THE PACKAGE INSERT:
Date of registration: 14 September 2012
Date of notification with regard to Regulation 9 & 10: 20 February 2015

SKEDULERINGSTATUS:
S4

EIENDOMSNAAM EN DOSEERVORM:
BIO METRONIDAZOLE IV (Intraveneuse Infusie)

SAMESTELLING:
Elke 100 ml oplossing bevat 500 mg metronidasool.
Onaktiewe bestanddele: Natriumchloried, natriumfosfaat anhidries, sitroensuur monohidraat en water vir inspuiting.

FARMAKOLOGIESE KLASSIFIKASIE:
A. 20.2 Ander antibiotikum.

FARMAKOLOGIESE AKSIE:
Farmakodinamiese eienskappe
Metronidasool is 'n voorlopergeneesmiddel; dit vereis reduktiewe aktivering van die stikstof-groep deur vatbare organismes. Die moederverbinding penetreer die selmembraan sonder om te verander, maar as die middel eers binne die sel is, word die stikstof-groep onder die redokstoestande wat in die anaërobe sel teenwoordig is, verminder. Gereduseerde metronidasool wat sitotoksies is, maar wel 'n kortstondige leeftyd het, ondergaan 'n wisselwerking met DNS om die heliks struktuur te verander, die string te verbreek met gevolglike inhibering van nukleïensuur sintese en seldood. Metronidasool besit bakterisidiese aktiwiteit teen anaërobe bakterieë.
Metronidasool toon antiprotosoale aktiwiteit teenoor Trichomonas vaginalis en ander protosoa, insluitende Entamoeba histolytica en Giardia lamblia. Dit affekteer nie die asidofiliese flora van die vagina nie en het geen uitwerking op Candida-spesies nie. Metronidasool beïnvloed nie die aktiwiteit van antibakteriële middels wat aktief is teen 'n verskeidenheid aërobe en fakultatiewe anaërobe nie. Metronidasool manifesteer antibakteriële aktiwiteit teen alle anaerobiese kokki en beide anaërobiese gram-negatiewe bacilli, insluitende Bacteriodes spesies, en anaërobiese spoorvormende gram-positiewe bacilli.
Farmakokinetiese eienskappe
Gelykvlak serum konsentrasies is ongeveer 25 µg/ml by die aanbevole intraveneuse dosisse. Metronidasool word versprei na die been, lewer en lewer absesse, longe, vaginale afskeidings, seminale vloeistowwe, gal, speeksel en borsmelk. Dit gaan ook deur die plasenta en die bloed-breinskans. Die halfleeftyd is ongeveer 8 ure in plasma en die verspreidingsvolume daarvan is ongeveer dit van die totale liggaamswater. Minder as 20 % van die middel word gebind aan plasmaproteïene. Terapeutiese konsentrasies word bereik in die serebrospinale vloeistof. Die lewer is die belangrikste area waar metabolisme plaasvind, met meer as 50 % van die sistemiese opruiming van metronidasool wat hier plaasvind. Die hidroksi-metaboliet het 'n halfleeftyd van 12 uur. Ongeveer 60 – 80 % word via die niere deur urine uitgeskei (20 % van hierdie hoeveelheid word onveranderd uitgeskei), en ongeveer 6 – 15 % is onaktiewe metaboliete in die stoelgang. Metronidasool en sy metaboliete word suksesvol verwyder deur hemodialise, maar nie so suksesvol deur peritoneale dialise nie.

INDIKASIES:
Vir die behandeling van infeksies waar anaërobe bakterieë as patogene geïdentifiseer of vermoed word, veral Bacteroides fragilis en ander bakteroïede spesies, insluitend ander spesies waarvoor BIO METRONIDAZOLE IV bakterisidies is, soos bv. streptokokkus, fusobakterieë, eubakterieë en clostridia, wanneer die orale roete nie geskik is nie.
a) BIO METRONIDAZOLE IV word gebruik vir anaërobiese infeksies tydens die volgende indikasies:
- post-operatiewe wond infeksies en
- pelviese inflammatoriese siekte.

Gekombineerde terapie word dikwels aangedui omdat hierdie toestande gewoonlik met gemengde infeksies geassosieer word.
b) BIO METRONIDAZOLE IV word ook gebruik in die voorkomende behandeling van post-operatiewe infeksies as gevolg van anaërobiese bakterieë:
Toegedien voor of na: (i) Appendisektomie,
(ii) Ginekologiese operasies en
(iii) Kolon operasies.

KONTRA-INDIKASIES:
Hipersensitiwiteit teenoor metronidasool en ander imidasole.
Swangerskap en laktasie.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
Pasiënte moet aangeraai word om nie alkohol tydens BIO METRONIDAZOLE IV behandeling en vir ten minste een dag daarna te gebruik nie, omdat daar disulfiram-agtige reaksies soos maagkrampe, naarheid, braking, hoofpyn en gloede in sekere pasiënte kan ontstaan. Die toediening van farmaseutiese produkte wat met alkohol geformuleer is, insluitende inspuitings, die drink van alkohol of die gepaardgaande gebruik van BIO METRONIDAZOLE IV en disulfiram verhoog die kanse om newe effekte te kry (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS). Akute psigose of verwarring is al geassosieer met die gelyktydige gebruik van BIO METRONIDAZOLE IV en disulfiram in alkoholiese pasiënte.
Pseudomembraneuse kolitis is al met die gebruik van BIO METRONIDAZOLE IV aangemeld. Perifere neuropatie, verbygaande epileptiese aanvalle en leukopenie gaan soms gepaard met verlengde en intensiewe behandeling met BIO METRONIDAZOLE IV. Alle pasiënte wat BIO METRONIDAZOLE IV vir langer as 10 dae ontvang, moet klinies en met laboratorium toetse gemonitor word, en indien tekens van perifere neuropatie of sentrale senuweestelsel toksisiteit ontwikkel, moet behandeling gestaak word. Dosisse moet verminder word in pasiënte met ernstige lewersiekte.
BIO METRONIDAZOLE IV moet met uiterste omsigtigheid gebruik word by pasiënte met bloeddiskrasieë of met aktiewe of kroniese siektes van die sentrale en perifere senuweestelsel.
BIO METRONIDAZOLE IV het anti-treponemale aktiwiteit en dit mag die immunologiese respons wat in onbehandelde vroeë sifilis gesien word, maskeer. Indien daar vermoed word dat pasiënte sifilis het tydens die behandeling met BIO METRONIDAZOLE IV, behoort hulle vir 'n addisionele 4 tot 8 weke ondersoek te word vir sifilis.
Bestuur van 'n motorvoertuig of uitvoering van gevaarlike take:
Pasiënte behoort gewaarsku te word teen die moontlikheid van verwarring, duiseligheid, hallusinasies, konvulsies of visuele afwykings. Indien die toestande voorkom, word die pasiënt aangeraai om nie motorvoertuie te bestuur of masjinerie te beheer nie.

INTERAKSIES:
Daar is al aangemeld dat BIO METRONIDAZOLE IV die metabolisme of uitskeiding van verskeie medisyne benadeel insluitende warfarien, fenitoïen, litium en fluorourasiel, met die gevolglike potensiaal vir 'n verhoogde voorkoms van nadelige gevolge. Daar is ook bewyse dat fenitoïen die metabolisme van BIO METRONIDAZOLE IV mag versnel.
Plasmakonsentrasies van BIO METRONIDAZOLE IV is verlaag deur gelyktydige toediening van fenobarbitoon, met 'n gevolglike verlaging in die doeltreffendheid van BIO METRONIDAZOLE IV. Simetidien het al plasmakonsentrasies van BIO METRONIDAZOLE IV verhoog en dit mag die risiko van neurologiese newe-effekte verhoog. BIO METRONIDAZOLE IV mag die risiko van 'n styging in siklosporienvlakke, verhoog. Wanneer BIO METRONIDAZOLE IV saam met alkohol geneem word, mag dit disulfiram-agtige sowel as akute psigose of verwarring in sommige pasiënte ontlok (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS). Daar bestaan 'n moontlikheid dat litium konsentrasies kan verhoog (met die aanvangsbehandeling van BIO METRONIDAZOLE IV), dus moet serum litium- en kreatinienvlakke sorgvuldig gemonitor word na die aanvang van behandeling om enige litium toksisiteit vas te stel.

SWANGERSKAP EN LAKTASIE:
Veiligheid tydens swangerskap en laktasie is nog nie vasgestel nie.

DOSERING EN GEBRUIKSAANWYSINGS:
Behandeling van anaërobiese infeksies:
Dosering van volwassenes en adolessente (bo 12 jaar):
100 ml (500 mg/100 ml) elke 8 uur deur intraveneuse infusie. Die inspuiting moet intraveneus toegedien word teen 'n dosis van 5 ml per minuut, maar kan ook alleen of gelyktydig toegedien word (as aparte inspuiting) saam met ander bakteriologies toepaslike antibakteriese middels in parenterale doseervorme.
Dosering van kinders onder 12 jaar:
Soos in dosering van volwassenes, maar die enkele intraveneuse dosis word gebaseer op 1,5 ml (7,5 mg BIO METRONIDAZOLE IV)/kg liggaamsmassa en die orale dosis van 7,5 mg/kg liggaamsmassa.
Voorkomende gebruik:
Dosering van volwassenes en adolessente (bo 12 jaar):
100 ml (500 mg/100 ml) deur intraveneuse infusie dadelik voor, gedurende of na 'n operasie, gevolg deur dieselfde dosis elke 8 ure totdat orale medikasie geneem kan word.
Dosering van kinders onder 12 jaar:
Soos in dosering van volwassenes, maar die enkele intraveneuse dosis word gebaseer op 1,5 ml (7,5 mg BIO METRONIDAZOLE IV)/kg liggaamsmassa en die orale dosis van 7,5 mg/kg liggaamsmassa.
BIO METRONIDAZOLE IV kombinering:
BIO METRONIDAZOLE IV is verenigbaar met die volgende inspuitings:
Natriumchloried inspuiting 0,9 % m/v (gewone soutoplossing inspuiting)
Dekstrose 5 % m/v inspuiting
Steriele water vir inspuiting
Bakteriostatiese water vir inspuiting
Bakteriostatiese natriumchloried 0,9 %
Ringer's laktaat inspuiting

NEWE-EFFEKTE:
Afwykings van die senuweestelsel
Algemeen: Sentrale senuweestelsel (SSS) gevolge soos duiseligheid of lighoofdigheid; hoofpyn.
Minder dikwels: Perifere neuropatie, gewoonlik in die vorm van gevoelloosheid of prikkelende gevoel in die ledemate, en konvulsies is ernstige newe effekte wat geassosieer word met hoë dosisse of langdurige behandeling. SSS toksisiteit soos ataksia, lompheid of wankelrigheid; ensefalopatie – gemoedstoestand of geestelike veranderinge soos depressie of verwardheid en aanvalle / konvulsies.
Frekwensie onbekend: Swakheid. Psigotiese versteurings insluitende verwarring, irritasie en hallusinasies; lomerigheid; slaaploosheid.
Algemene afwykings geassosieer met die plek van toediening
Minder dikwels: Verandering in smaak sensasie; droë mond; onaardige of skerp metaal smaak; tromboflebitis wat manifesteer as pyn, gevoeligheid, rooiheid of swelling by die inspuitplek.
Immuunsisteem afwykings
Minder dikwels: Hipersensitiwiteit wat manifesteer as 'n veluitslag, koors, angio-edeem, galbulte, gloede, of urtikarie, pruritis, anafilakse.
Frekwensie onbekend: Matige eritemateuse uitbarstings, met vlietende gewrigspyn wat lyk soos serum siekte kan voorkom.
Bloed afwykings
Minder dikwels: Leukopenie (seer keel en koors); trombositopenie.
Frekwensie onbekend: Agranulositose, neutropenie.
Endokriene afwykings
Minder dikwels: Pankreatitis.
Renale en urinêre afwykings
Minder dikwels: Urienweg gevolge soos disurie, verhoogde urinêre frekwensie, gereelde of pynlike urinering; onvermoë om die vloei van urine te beheer; gevoel van pelviese druk, donker urine.
Infeksies en infestasies
Minder dikwels: Vaginale kandidiase.
Gastro-intestinale afwykings
Algemeen: Gastro-intestinale versteurings.
Frekwensie onbekend: Antibiotika-geassosieerde kolitis, pseudomembraneuse kolitis. Naarheid, verlies van eetlus en smaak versteurings; naarheid word somtyds vergesel deur hoofpyn, anoreksie en braking. Diarree, droë mond, 'n harige tong en stomatitis mag voorkom.
Vel en subkutaneuse weefsel afwykings
Frekwensie onbekend: Veluitslag. Pustulêre uitbarstings mag voorkom.
Muskuloskeletale, bindweefsel en beenafwykings
Frekwensie onbekend: Mialgie, artralgie.
Oogafwykings:
Frekwensie onbekend: Verbygaande gesigsteurnisse soos diplopie en miopie is aangemeld.
Hepatobiliêre afwykings
Frekwensie onbekend: Verhoogde lewerensiemwaardes is al aangemeld. Gevalle van omkeerbare abnormale lewerfunksie en cholestatiese hepatitis is aangemeld.

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Sien NEWE EFFEKTE EN WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS.
Daar is geen spesifieke teenmiddel vir oordosering nie. Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
'n Helder, kleurlose tot liggeel oplossing. Die oplossing is steriel en vry van enige deeltjies.

AANBIEDING:
BIO METRONIDAZOLE IV word verpak in 'n 100 ml wit, deursigtige LDPE bottel.
Elke bottel is toegedraai met 'n deursigtige helder polipropileen omslag.

BERGINGSAANWYSINGS:
Bewaar by of benede 30 °C. Moet dit nie in die yskas berg nie.
Slegs vir enkele gebruik. Gooi enige oorblywende inhoud weg na gebruik.
Beskerm teen lig.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIE NOMMER:
42/20.2/0567

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