SCHEDULING STATUS:
S5

PROPRIETARY NAME AND DOSAGE FORM:
BIO ZOPICLONE 7,5 (Film coated tablet)

COMPOSITION:
Each film coated tablet contains zopiclone 7,5 mg.
BIO ZOPICLONE 7,5 contains the following inactive ingredients: glycerol, hypromellose, magnesium stearate, maize starch, mannitol, microcrystalline cellulose, polysorbate 80, povidone, sucrose and the colourant titanium dioxide.
BIO ZOPICLONE 7,5 film-coated tablets contain mannitol and sucrose.

PHARMACOLOGICAL CLASSIFICATION:
A 2.2 Sedatives, hypnotics

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Zopiclone is a cyclopyrrolone hypnotic agent. It has sedative, anxiolytic, muscle relaxant, hypnotic and anticonvulsant properties. These effects are related to a specific agonist action at central receptors belonging to the gamma-aminobutyric acid (GABA) macromolecular complex in the brain, modulating the opening of the chloride ion channel.
Pharmacokinetic properties
Absorption:
Zopiclone is rapidly absorbed. Peak concentrations (30 to 60 ng/ml after doses of 3,75 mg and 7,5 mg) are reached within 1,5 to 2 hours. Absorption is not affected by co-administration with food.
Distribution:
Plasma protein binding is weak (approximately 45 %) and non-saturable. Zopiclone is distributed into breast milk, its concentration being approximately 50 % that of plasma concentrations.
Metabolism:
Zopiclone is extensively metabolised in humans to two major metabolites, N-oxide zopiclone (pharmacologically active in animals) and N-desmethyl zopiclone (pharmacologically inactive in animals). An in vitro study indicates that cytochrome P450 (CYP3A4) is the major isoenzyme involved in the metabolism of zopiclone to both metabolites, and that CYP2C8 is also involved with N-desmethyl zopiclone formation.
Elimination:
At recommended doses, the elimination half-life of the zopiclone is approximately 5 hours. Approximately 80 % of zopiclone is eliminated renally, mainly in the form of free metabolites (N-oxide and N demethyl derivates). Faecal elimination is approximately 16 %.
After repeated administration there is no accumulation of zopiclone and its metabolites. Inter-individual variations appear to be low.
Special Population:
In renal insufficiency, no accumulation of zopiclone or its metabolites has been detected after prolonged administration.
In cirrhotic patients, the plasma clearance of zopiclone is reduced by approximately 40 % in relation to the decrease of the demethylation process. Therefore, dosage will have to be modified in these patients.
In elderly patients, notwithstanding a slight decrease in hepatic metabolism and lengthening of elimination half-life to approximately 7 hours, various studies have not shown plasma accumulation of the medicine on repeated dosing.

INDICATIONS:
BIO ZOPICLONE 7,5 is indicated for the short-term treatment of insomnia in adults when the disorder is severe, disabling or subjecting the individual to extreme stress.

CONTRAINDICATIONS:
BIO ZOPICLONE 7,5 is contraindicated in patients with:
Hypersensitivity to zopiclone or any of the other ingredients in this product.
Respiratory failure.
Severe sleep apnoea syndrome.
Severe hepatic insufficiency.
Myasthenia gravis.
BIO ZOPICLONE 7,5 should not be used in children under the age of 18 years.
Safety in pregnancy and lactation has not been established (see PREGNANCY AND LACTATION).
Pre-existing central nervous system depression and coma.

WARNINGS AND SPECIAL PRECAUTIONS:
BIO ZOPICLONE 7,5 may lead to drowsiness and impaired concentration, which may be aggravated by simultaneous intake of alcohol or other central nervous system depressants. Patients should be warned against driving motor vehicles or operating machinery or performing potentially hazardous tasks where loss of concentration may lead to accidents.
BIO ZOPICLONE 7,5 should be used with extreme caution in patients with a history of drug or alcohol abuse.
Dependence:
There is a potential for abuse and the development of physical and psychological dependence, especially with prolonged use and high doses. The risk of dependence is also greater in patients with a history of alcohol or drug abuse. Once physical dependence has developed, abrupt termination of therapy will result in a withdrawal syndrome presenting with headaches, muscle pain, extreme anxiety, tension, restlessness, confusion and irritability. *In severe cases the following symptoms may occur:* derealisation, depersonalisation, hyperacusis (abnormal acute hearing), numbness and tingling of extremities, hypersensitivity to light, noise and physical contact, hallucinations or epileptic seizures.
Rebound insomnia and withdrawal phenomena :
A risk of such phenomena is greater after abrupt discontinuation of BIO ZOPICLONE 7,5, especially after prolonged treatment. It is, therefore, recommended to decrease the dosage gradually and to advise patient accordingly (see also SIDE EFFECTS).
Some loss of efficacy of BIO ZOPICLONE 7,5 may develop after repeated use.
To minimise the risk of anterograde amnesia and mental confusion, BIO ZOPICLONE 7,5 should be taken only when the patient's schedule will allow for a full night's sleep (7 to 8 hours).
BIO ZOPICLONE 7,5 should not be used alone to treat depression or anxiety with depression, as suicide may be precipitated in these patients.
BIO ZOPICLONE 7,5 is not recommended for primary treatment of psychotic illness.
Effects on ability to drive and use machines:
BIO ZOPICLONE 7,5 may adversely affect the ability to drive or use machines. The risk is increased by concomitant intake of alcohol (see WARNINGS AND SPECIAL PRECAUTIONS above).

PREGNANCY AND LACTATION:
Insufficient data is available on BIO ZOPICLONE 7,5 to assess its safety during human pregnancy and lactation. If BIO ZOPICLONE 7,5 is used during the last three months of pregnancy or during labour, due to pharmacological action of the product, effects on the neonate, such as hypothermia, hypotonia, and respiratory depression can be expected.
The use of BIO ZOPICLONE 7,5 during pregnancy is not recommended (see CONTRAINDICATIONS).
If BIO ZOPICLONE 7,5 is prescribed to a woman of childbearing potential, she should be warned to contact her medical practitioner regarding discontinuation of the product if she intends to become or suspects that she is pregnant.
BIO ZOPICLONE 7,5 is distributed in the breast milk. BIO ZOPICLONE 7,5 should not be used by breastfeeding mothers. (See CONTRAINDICATIONS)

DOSAGE AND DIRECTIONS FOR USE:
BIO ZOPICLONE 7,5 therapy should be used for as short a time as possible. Generally the duration of treatment varies from a few days to two weeks, with a maximum, including tapering off process, of four weeks. Use for any longer periods requires re-evaluation of the patient.
Treatment should be started with the lowest recommended dose and the maximum dose should not be exceeded.
Adults: 7,5 mg orally, shortly before retiring. This dose should not be exceeded.
Elderly patients and patients with impaired hepatic function or chronic respiratory insufficiency: The lower dose of 3,75 mg BIO ZOPICLONE 7,5 should be used initially in these patients, and if necessary, the dose may be increased to 7,5 mg.
Renal insufficiency: Patients with impaired function should start treatment with 3,75 mg, although accumulation of BIO ZOPICLONE 7,5 or its metabolites has not been seen during treatment of insomnia in patients with renal insufficiency.

SIDE EFFECTS:
Nervous system disorders
Frequent: Dizziness, headache, confusion, residual somnolence, impaired coordination, anterograde amnesia (especially when sleep is interrupted, or when tablet is taken too early before retiring), (see WARNINGS AND SPECIAL PRECAUTIONS). Drowsiness and incoordination on waking, mental depression. Dysarthria (slowed/slurred speech).
Less Frequent: Nightmares, irritability, hallucinations, aggressiveness and inappropriate behaviour possibly associated with amnesia, drowsiness, abnormal thoughts, asthenia, speech disorders, tremor, agitation, anxiety, nervousness.
Gastrointestinal disorders
Frequent: Bitter taste in the mouth, dry mouth, dyspepsia, anorexia, weight loss or gain, constipation.
Less Frequent: Nausea, vomiting.
Skin and subcutaneous tissue disorders:
Less Frequent: Pruritus, rash (may be a sign of hypersensitivity), paraesthesia.
Respiratory, thoracic and mediastinal disorders
Less Frequent: Dyspnoea (difficulty breathing)
Cardiac disorders
Less Frequent: Palpitations
Vascular disorders
Less Frequent: Hypotension
Blood and the lymphatic system disorders
Less Frequent: Blood disorders
Renal and urinary disorders
Less Frequent: Urinary retention, incontinence
Reproductive system and breast disorders
Less Frequent: Changes in libido
Hepato-biliary disorders
Less Frequent: Jaundice
Immune system disorders
Less Frequent: Hypersensitivity reactions
General disorders
Less Frequent: Chills, sweating.
Other
The following side effects have been reported and frequencies are unknown:
Rebound effects: Discontinuation of treatment of BIO ZOPICLONE 7,5 may result in a transient syndrome of anxiety, restlessness and mood changes, as well as an enhancement of symptoms that led to the treatment with BIO ZOPICLONE 7,5 (see DIRECTIONS FOR USE)

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
Symptoms of overdose:
(See SIDE EFFECTS)
Overdose is usually manifested by varying degrees of central nervous system depression according to the quantity ingested. In mild cases, symptoms include drowsiness, confusion, and lethargy; in more serious cases, symptoms may include ataxia, hypotonia, hypotension, respiratory depression and coma. Overdose may be life-threatening especially when combined with other CNS depressants (including alcohol). Other risk factors such as the presence of concomitant illness and the debilitated state of the patient may contribute to the severity of the symptoms and can result in fatal outcome.
Treatment of overdose:
Symptomatic and supportive treatment in an adequate clinical environment is recommended, with special attention being paid to respiratory and cardiovascular functions.
Gastric lavage is only useful when performed soon after ingestion.
Haemodialysis is of no value due to the large volume of distribution of BIO ZOPICLONE 7,5. Flumazenil may be a useful antidote.

IDENTIFICATION:
White, almost white film coated oblong, bulged tablets with breaking notch on both sides.

PRESENTATION:
BIO ZOPICLONE 7,5 are packed as 30 tablets in white HDPE container with white HDPE cap or in white opaque PVC/PVDC/Aluminium blister strips, kept in an outer carton, each strip containing ten tablets.

STORAGE INSTRUCTIONS:
Store in a cool, dry place at or below 25 °C. Protect from light.
For HDPE Container: Keep well closed
Do not remove blisters from outer container until required for use.
KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:
42/2.2/0537

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:
Biotech Laboratories (Pty) Ltd
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SKEDULERINGSTATUS:
S5

EIENDOMSNAAM EN DOSEERVORM:
BIO ZOPICLONE 7,5 (Filmbedekte tablet)

SAMESTELLING:
Elke filmbedekte tablet bevat zopikloon 7,5 mg.
BIO ZOPICLONE 7,5 bevat die volgende onaktiewe bestanddele: gliserol, hipromellose, magnesium stearaat, mieliestysel, mannitol, mikrokristalagtige sellulose, polisorbaat 80, povidoon, sukrose en titaandioksied as kleurmiddel.
BIO ZOPICLONE 7,5 filmbedekte tablette bevat mannitol en sucrose.

FARMAKOLOGIESE KLASSIFIKASIE:
A.2.2 Kalmeermiddels, verdowingsmiddels

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Zopikloon is 'n siklopirroloniese verdowingsmiddel. Dit het kalmerende, angsiolitiese, spierverslappende, hypnotise en antikonvulsante eienskappe. Hierdie effek hou verband met 'n spesifieke agonistiese aksie by die sentrale reseptors wat tot die gamma-aminobutiriese suur (GABS) makromolekulêre kompleks in die brein behoort, wat die opening van die chloried-ioon kanaal moduleer.
Farmakokinetiese eienskappe
Absorpsie:
Zopikloon word vinnig absorbeer. Piek konsentrasies (30 tot 60 ng/ml na dosisse van 3,75 mg en 7,5 mg) word binne 1,5 tot 2 ure bereik. Absorpsie word nie geaffekteer deur die gelyktydige inname van voedsel nie.
Distribusie:
Plasmaproteien binding is swak (ongeveer 45 %) en is onversadigbaar. Zopikloon versprei na borsmelk, in konsentrasies van ongeveer 50 % van die van die plasmakonsentrasie.
Metabolisme:
Zopikloon word grootliks in mense metaboliseer deur twee hoof metaboliete, naamlik N-oksied zopikloon (farmakologies aktief in diere) en N-desmetiel zopikloon (farmakologies onaktief in diere). 'n In vitro studie toon aan dat sitochroom P450 (CYP3A4) die hoof iso-ensiem is wat betrokke is by die metabolisme van zopikloon tot beide metaboliete en dat CYP2C8 ook betrokke is by die formasie van N-demetiel zopikloon.
Uitskeiding:
Teen voorgestelde dosisse is die halfleeftyd van zopikloon ongeveer 5 ure. Ongeveer 80 % van zopikloon word urinêr uitgeskei, hoofsaaklik in die vorm van vrye metaboliete (N-oksies en N-demetiel). Fekale uitskeding is ongeveer 16 %.
Na herhaalde toediening is daar geen akkumulasie van zopikloon of sy metaboliete nie. Inter-individuele variasies blyk laag te wees.
Uitsonderingsgroepe:
In renale ontoereikendheid is geen akkumulasie van zopikloon of sy metaboliete waargeneem na langdurige toediening nie.
In sirotiese pasiënte word die plasmaopklaring van zopikloon verminder met ongeveer 40 % met betrekking tot die afname van die demetieleringsproses, dus moet die dosis in hierdie pasiënte aangepas word.
In bejaarde pasiënte, nieteenstaande 'n geringe afname in hepatiese metabolisme en die verlenging van uitskeidings halfleeftyd tot ongeveer 7 ure, het verskeie studies geen plasma akkumulasie van die medisyne na herhaalde toediening getoon nie.

INDIKASIES:
BIO ZOPICLONE 7,5 is aangedui vir die korttermyn behandeling van slapeloosheid in volwassenes wanneer die versteuring die individu aan geweldige stress blootstel, hewig of stremmend is.

KONTRA-INDIKASIES:
BIO ZOPICLONE 7,5 word gekontra-indikeer in pasiënte met:
Hipersensitiwiteit vir zopikloon of enige van die ander bestanddele van hierdie produk.
Respiratoriese versaking.
Erge slaapapnee sindroom.
Erge hepatiese ontoereikendheid.
Myasthenia gravis.
BIO ZOPICLONE 7,5 behoort nie deur kinders onder die ouderdom van 18 jaar gebruik te word nie.
Veiligheid tydens swangerskap en laktasie is nie vasgestel nie (sien SWANGERSKAP EN LAKTASIE).
Voorafbestaande sentralesenustelsel depressie en koma.

WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS:
BIO ZOPICLONE 7,5 kan lei tot lomerigheid en verswakte konsentrasie, wat vererger kan word deur die gelyktydige inname van alkohol of ander sentralesenustelsel onderdrukkers. Pasiënte moet gewaarsku word teen die bestuur van motorvoertuie, die beheer van masjienerie, en die uitvoer van potensieel gevaarlike take waartydens verswakte konsentrasie tot ongelukke kan lei. BIO ZOPICLONE 7,5 moet met uiterste omsigtigheid gebruik word in pasiënte met 'n geskiedenis van dwelm- of alkoholmisbruik.
Afhanklikheid:
Daar bestaan 'n potensiaal vir die misbruik en die ontwikkeling van 'n fisiese en psigologiese afhanklikheid, veral in die geval van langdurige gebruik en hoë dosisse. Die risiko van afhanklikheid is ook groter in pasiënte met 'n geskiedenis van alkohol- of dwelmmisbruik. Sodra fisiese afhanklikheid ontwikkel het, sal die onmiddelike staking van behandeling 'n onttrekkingsindroom tot gevolg hê.
Dit sluit die volgende simptome in: hoofpyne, spierpyne, geweldige angstigheid, spanning, rusteloosheid, verwardheid en prikkelbaarheid. In erge gevalle kan die volgende simptome voorkom: derealisasie, ontpersoonliking, hiperakusis (abnormale akute gehoor), gevoeloosheid en tinteling van die ledemate, hipersensitiwiteit tot lig, geraas en fisiese aanraking, hallusinasies en of epileptiese stuipe.
Terugslag slapeloosheid en ontrekkingsverskynsels:
Die risiko van hierdie verskynsel is groter indien BIO ZOPICLONE 7,5 skielik gestaak word, veral na langdurige behandeling. Dit word dus aanbeveel dat die dosis geleidelik verminder word en dat die pasiënt dienooreenkomstig ingelig word (sien ook NEWE-EFFEKTE).
Die verlies van doeltreffendheid van BIO ZOPICLONE 7,5 kan ontwikkel na herhaalde gebruik. Om die risiko van anterograde geheueverlies en geestesverwarrendheid te minimaliseer, moet BIO ZOPICLONE 7,5 slegs geneem word indien die pasiënt se skedule 'n volle nag se slaap (7 tot 8 ure) toelaat.
BIO ZOPICLONE 7,5 moet nie alleen gebruik word om depressie en angstigheid met depressie te behandel; dit kan aanleiding gee tot selfmoord in hierdie pasiënte.
BIO ZOPICLONE 7,5 word nie aanbeveel as die primêre behandeling vir psigotiese siektes nie.
Effek op die vermoë om te bestuur en masjienerie te bedryf:
BIO ZOPICLONE 7,5 kan die vermoë om te bestuur en masjienerie te beryf nadelig beïnvloed. Hierdie risiko word verhoog deur die gelyktydige inname van alkohol (sien WAARSKUWINGS EN SPESIALE VOORSORGMAATREËLS).

SWANGERSKAP EN LAKTASIE:
Onvoldoende inligting van BIO ZOPICLONE 7,5 is beskikbaar ten einde die veiligheid gedurende menslike swangerskap en laktasie vas te stel. Indien BIO ZOPICLONE 7,5 gedurende die laaste drie maande van swangerskap of gedurende geboorte toegedien word, kan gevolge soos hipotermie, hipotonie en respiratoriese depressie in die neonaat verwag word. Dit is te wyte aan die farmakologiese uitwerking van die produk.
Die gebruik van BIO ZOPICLONE 7,5 gedurende swangerskap word nie aanbeveel nie. (Sien KONTRA-INDIKASIES).
Indien BIO ZOPICLONE 7,5 aan 'n vrou met die potensiaal om swanger te raak voorgeskryf word, moet sy gewaarsku word om haar mediese praktisyn te kontak rakende die staking van die produk indien sy van voorneme is om swanger te raak of indien sy vermoed dat sy reeds swanger is.
BIO ZOPICLONE 7,5 versprei na borsmelk. BIO ZOPICLONE 7,5 moet nie deur vrouens wat borsvoed gebruik word nie (sien KONTRA-INDIKASIES).

DOSIS EN GEBRUIKSAANWYSINGS:
BIO ZOPICLONE 7,5 behandeling moet vir die kortste moontlike typerk wees. In die algemeen varieer die duur van die behandeling vanaf 'n paar dae tot twee weke, met 'n maksimum van vier weke, wat die tydperk van geleidelike vermindering van dosis insluit. Gebruik vir langer periodes vereis herevaluering van die pasiënt.
Behandeling moet begin word met die laagste voorgestelde dosis en die maksimum dosis moet nie oorskry word nie.
Volwassenes: 7,5 mg, mondeliks toegedien kort voor slapenstyd. Hierdie dosis moet nie oorskry word nie.
Bejaarde pasiënte en pasiënte met ingekorte hepatiese funksie of chroniese respiratoriese ontoereikendheid: Die verminderde dosis van 3,75 mg BIO ZOPICLONE 7,5 moet aanvanklik in hierdie pasiënte gebruik word, en indien nodig kan die dosis verhoog word tot 7,5 mg.
Renale ontoereikendheid: Pasiënte met ingekorte nierfunksie moet behandeling met 3,75 mg begin, alhoewel die akkumulasie van BIO ZOPICLONE 7,5 of sy metaboliete nie gedurende behandeling van slapeloosheid in pasiënte met renale ontoereikendheid opgemerk is nie.

NEWE-EFFEKTE:
Senuweestelsel versteurings
Dikwels: Duiseligheid, hoofpyn, verwardheid, residuele slaperigheid, ingekorte koördinasie, anterograde amnesie (veral wanneer slaap onderbreek word of indien die tablet te lank voor slapenstyd geneem word), (sien WAARSKUWINGS EN SPESIALE VOORSORFMAATREELS). Lomerigheid en inkoördinasie wanneer wakker word, geestesdepressie. Dysartria (vertraagde/onstuimige spraak).
Minder dikwels: Nagmerries, prikkelbaarheid, hallusinasies, aggressiwiteit en onvanpaste gedrag wat moontlik geassosieer kan word met amnesie, lomerigheid, abnormale gedagtes, astenie, spraakafwykings, bewing, agitasie, angstigheid, senuagtigheid.
Gastroïntestinale versteurings
Dikwels: Bitter smaak in die mond, droeë mond, dispepsie, anoreksie, gewigstoename of verlies, hardlywigheid.
Minder dikwels: Naarheid, braking.
Vel- en subkutane weefselafwykings
Minder dikwels: Pruritus, veluitslag (kan 'n teken van hipersensitiwiteit wees), parestesie.
Respiratoriese, torakale en mediastinale versteurings
Minder dikwels: Dispnee (moeilike asemhaling).
Kardiale versteurings
Minder dikwels: Palpitasies.
Vaskulêre versteurings
Minder dikwels: Hipotensie.
Bloed en limfstelsel versteurings
Minder dikwels: Bloed versteurings.
Urinêre versteurings
Minder dikwels: Urinêre retensie, inkontinensie.
Reproduktiewe stelsel en bors versteurings
Minder dikwels: Veranderings in libido.
Hepato-billiêre versteurings
Minder dikwels: Geelsug.
Imuunstelsel versteurings
Minder dikwels: Hipersensitiwiteits reaksies.
Algemene versteurings
Minder dikwels: Kouekoors, sweet.
Ander
Die volgende newe-effekte is aangemeld en is die frekwensie onbekend:
Terugslag effekte: Beëindiging van behandeling met BIO ZOPICLONE 7,5 kan 'n verbygaande angstigheidsindroom, rusteloosheid en buiveranderings sowel as 'n versterking van die simptome wat tot die behandeling met BIO ZOPICLONE 7,5 aanleiding gegee het, tot gevolg hê (sien GEBRUIKSAANWYSINGS).

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:
Simptome van oordosering:
(Sien NEWE-EFFEKTE)
Oordosering manifesteer gewoonlik deur variërende grade van sentralesenuweestelsel depressie ooreenstemmend met die hoeveelheid ingeneem. In matige gevalle sluit die simptome lomerigheid, verwarrendheid en lusteloosheid in. In ernstiger gevalle sluit die simptome ataksie, hipotonie, hipertensie en respiratoriese depressie en koma in. Oordosering kan lewensgevaarlik wees, veral indien dit met ander SSS depressante (insluitende alkohol) geneem word. Ander risiko faktore soos die teenwoordigheid van gepaardgaande siekte en die verswakte toestand van die pasiënt kan bydra tot die ernstigheidsgraad van die simptome en kan 'n noodlotting uitkoms tot gevolg hê.
Behandeling van oordosering:
Simptomatiese en ondersteunende behandeling in 'n toereikende kliniese omgewing word voorgestel, met spesiale aandag wat aan respiratoriese en kardiovaskulêre funksies geskenk word.
Maagspoeling is slegs nuttig indien dit kort na inname uitgevoer word. Haemodialise is van geen waarde nie gesien in die lig van die groot volume van verspreiding van BIO ZOPICLONE 7,5. Flumazenil kan as 'n nuttige teenmiddel dien.

IDENTIFIKASIE:
Wit, bykans wit filmbedekte langwerpige bult-tablette met 'n breek kerf aan beide kante.

AANBIEDING:
BIO ZOPICLONE 7,5 word verpak as 30 tablette in wit HDPE houers met 'n wit HDPE deksel of in opaak wit PVC/PVDC/Aluminium stulpverpakking, wat in 'n buitenste karton houer geberg word, waarvan elke stulpstrook tien tablette bevat.

BERGINGSAANWYSINGS:
Bewaar in 'n koel, droë plek teen of benede 25 °C. Beskerm teen lig
Ten opsigte van die HDPE houer: bewaar diggeslote.
Moet nie die stulpverpakking van die buitenste karton verwyder todat dit benodig word vir gebruik nie.
HOU BUITE DIE BEREIK VAN KINDERS.

REGISTRASIENOMMER:
42/2.2/0537

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