SCHEDULING STATUS:
S3

PROPRIETARY NAME AND DOSAGE FORM:
TORASEMIDE BIOTECH 5 Tablets
TORASEMIDE BIOTECH 10 Tablets
TORASEMIDE BIOTECH 20 Tablets

COMPOSITION:
TORASEMIDE BIOTECH 5: Each tablet contains 5,0 mg torasemide.
TORASEMIDE BIOTECH 10: Each tablet contains 10,0 mg torasemide.
TORASEMIDE BIOTECH 20: Each tablet contains 20,0 mg torasemide.
Excipients: Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone.
Contains sugar (lactose monohydrate).
The 5 mg tablet contains 79,00 mg, the 10 mg tablet contains 158,00 mg and the 20 mg tablet contains 316,00 mg lactose monohydrate, respectively.

PHARMACOLOGICAL CLASSIFICATION:
A 18.1 Diuretics.

PHARMACOLOGICAL ACTION:
Pharmacodynamic properties
Torasemide is a loop diuretic. It inhibits activity of the $Na^+K^+2Cl^-$ symporter in the thick ascending limb of the loop of Henle, thereby inhibiting reabsorption of renal sodium and chloride. Owing to the blockade of the $Na^+K^+2Cl^-$ symporter, torasemide increases urinary Na^+ and Cl^- excretion profoundly.
Torasemide lowers blood pressure initially by reducing plasma and extracellular fluid volume; cardiac output also decreases. Eventually, cardiac output returns to normal with an accompanying decrease in peripheral resistance.
Pharmacokinetic properties
Torasemide is well absorbed following oral administration; not affected by food. The bio-availability is approximately 80 %. The volume of distribution (VolD) is 0,14 to 0,19 ℓ per kg. Torasemide has high protein binding properties ranging from 97 % to greater than 99 %.
Torasemide is metabolised via the hepatic cytochrome P-450 system to 5 metabolites. The major metabolite, M5, is pharmacologically inactive. Overall, torasemide appears to account for 80 % of the total diuretic activity, while metabolites M1 and M3 account for 9 % and 11 % respectively.
The elimination half-life of torasemide is 2,2 to 3,8 hours; not affected by moderate renal failure.
The onset of the diuretic action of torasemide is within 1 hour after oral administration. Time to peak concentration is 1 to 2 hours. Duration of the diuretic action is 6 to 8 hours.
Elimination is via the renal route, 24 % as parent compound. Torasemide is not significantly removed by haemodialysis.

INDICATIONS:
Essential hypertension. Oedema of cardiac and hepatic origin. Pulmonary oedema due to acute cardiac insufficiency.

CONTRAINDICATIONS:
- hypersensitivity to torasemide or any of the other ingredients of TORASEMIDE BIOTECH
- renal failure with absence of urine production (anuria)
- hepatic pre-coma and coma
- pregnancy and lactation
- patients with known hypersensitivity to sulfonylureas
- hypovolaemia
- hyponatraemia, hypokalaemia
- severe disorders of micturition (e.g. prostate hypertrophy)

TORASEMIDE BIOTECH should not be used in children of 12 years or younger.

WARNINGS and SPECIAL PRECAUTIONS:
TORASEMIDE BIOTECH should not be given in pre-comatose states associated with hepatic cirrhosis.
TORASEMIDE BIOTECH should be used with care in patients with prostatic hyperplasia or impairment of micturition since it can precipitate acute urinary retention.
Careful monitoring of the carbohydrate metabolism is recommended in patients with latent or manifest diabetes mellitus, since a rise in blood glucose may occur.
Long term treatment with TORASEMIDE BIOTECH requires regular monitoring of the electrolyte balance, glucose, uric acid, creatinine and lipid levels.
Careful monitoring is required in patients with a tendency to hyperuricaemia and gout.
Patients with rare hereditary problems of lactose- or glucose intolerance, the Lapp lactase deficiency of glucose-galactose malabsorption should not take TORASEMIDE BIOTECH.
Effects on ability to drive and use machines:
Individually varying reactions can impair alertness (e.g. patient's ability to drive vehicles or to operate machinery). This applies particularly when beginning treatment, switching from another medicine or starting a new co-medication and in conjunction with alcohol.

INTERACTIONS:
The effect of antihypertensive medicines may be potentiated when used in combination with TORASEMIDE BIOTECH.
Consecutive treatment or start of a new co-medication with an ACE-inhibitor may result in an excessive fall in blood pressure.
The action of antidiabetic medicines may be reduced by TORASEMIDE BIOTECH. Dosage adjustment of hypoglycaemic medications may be necessary.
Concurrent and/or sequential administration with TORASEMIDE BIOTECH and amphotericin B parenteral should be avoided since the potential for nephrotoxicity may be increased, especially in the presence of renal function impairment.
Anti-inflammatory medicines, NSAIDs, especially indomethacin may reduce the natriuretic action of TORASEMIDE BIOTECH.
When using TORASEMIDE BIOTECH simultaneously with digoxin, a potassium and/or magnesium deficiency may increase the sensitivity of the cardiac muscle to digoxin.
Concurrent use of lithium with TORASEMIDE BIOTECH may promote lithium toxicity because of reduced renal clearance.
Probenecid may reduce the diuretic activity of TORASEMIDE BIOTECH. The risk of hypokalaemia may be increased by TORASEMIDE BIOTECH.
The kalidiuretic effect of mineralo- and glucocorticosteroids and laxatives may be increased.
TORASEMIDE BIOTECH may potentiate the damaging effects of aminoglycocide antibiotics, cisplatin preparations and cephalosporins on the ear and kidney especially at high dose therapy.
The action of curare containing muscle relaxants and of theophylline can be potentiated by TORASEMIDE BIOTECH.
TORASEMIDE BIOTECH may decrease arterial responsiveness to pressor agents, e.g. epinephrine (adrenaline) and norepinephrine (noradrenaline).
In patients receiving high doses of salicylates, salicylate-toxicity may be increased by TORASEMIDE BIOTECH.
On concomitant treatment with cholestyramine, bioavailability and thus the efficacy of TORASEMIDE BIOTECH may be reduced.
The anticoagulant effects of warfarin or heparin may be decreased when these medicines are used concurrently with TORASEMIDE BIOTECH.
The concurrent use of sympathomimetics with TORASEMIDE BIOTECH may reduce the antihypertensive effects of TORASEMIDE BIOTECH.

PREGNANCY AND LACTATION:
Safety and efficacy in pregnant women have not been established. It is not known whether TORASEMIDE BIOTECH is distributed into breast milk. See CONTRAINDICATIONS.

DOSAGE AND DIRECTIONS FOR USE:
Essential hypertension:
Treatment is initiated with 2,5 mg TORASEMIDE BIOTECH per day. The usual maintenance dose is 2,5 mg per day. If this is insufficiently effective, the dose can be doubled to 5,0 mg per day. Higher doses will not lead to a further reduction of blood pressure.
Oedema of cardiac, hepatic and renal origin:
Treatment is initiated with 5,0 mg TORASEMIDE BIOTECH per day. The usual maintenance dose is 5,0 mg per day. If this is insufficiently effective, the dose can be increased up to 20 mg per day depending on the severity of the disease. In individual cases as much as 40 mg TORASEMIDE BIOTECH per day has been administered. Oral TORASEMIDE BIOTECH may be taken with some liquid on an empty stomach or at any time in relation to a meal, as convenient.

SIDE EFFECTS:
Immune system disorders
Less frequent: Acute hypersensitivity reactions (which may be life-threatening).
Metabolism and nutrition disorders
Less frequent: Disturbances of water and electrolyte balance, lowered potassium levels, a rise in blood urea and creatinine, increases in Gamma-GT, alteration in the blood glucose and lipid metabolism and a rise in the uric acid level.
Nervous system disorders
Frequency unknown: Signs of electrolyte and volume deficiency such as headache, dizziness, feelings of weakness, loss of appetite and cramps, confusional states, paraesthesia.
Gastrointestinal disorders
Frequent: Gastrointestinal symptoms (nausea, vomiting, diarrhoea, constipation).
Frequency unknown: Dry mouth
Renal and urinary disorders
Frequency unknown: In patients with urinary obstructions, e.g. prostate hypertrophy, increased urine production can lead to urine retention resulting in distension of the bladder.
Blood and the lymphatic system disorders
Less frequent: Treatment with TORASEMIDE BIOTECH may cause a decrease in the corpuscular constituents of the blood (erythrocytes, leucocytes, platelets).
Vascular disorders
Less frequent: Hypotension.
Cardiac disorders
Frequency unknown: Thromboembolic complications and cardiac or cerebral ischaemia or myocardial infarction.
Skin and subcutaneous tissue disorders
Less frequent: Allergic skin reactions, e.g. pruritus and exanthema or photosensitisation.
Eye disorders
Frequency unknown: Visual disturbances.
Ear disorders
Less frequent: Ototoxicity (ringing or buzzing in ears or loss of hearing).

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:
In the event of overdosage there may be a marked diuresis with the danger of loss of liquids and electrolytes which may lead to somnolence and confusion, hypotension, circulatory collapse and gastrointestinal symptoms. No specific antidote is known. Symptoms of overdosage generally disappear on reduction of the dose or withdrawal of the medicine and simultaneous replacement of fluid and electrolytes (to be monitored). Treatment is symptomatic and supportive.

IDENTIFICATION:
TORASEMIDE BIOTECH 5: White to off white, oval shaped, scored tablets, debossed with '5' on plain side and scored on other side.
TORASEMIDE BIOTECH 10: White to off white, oval shaped, scored tablets, debossed with "10" on plain side and scored on other side.
TORASEMIDE BIOTECH 20: White to off-white, oval shaped, scored tablets, debossed with "20" on plain side and scored on other side.

PRESENTATION:
TORASEMIDE BIOTECH 5 & 10:
30 and 100 tablets are packed in white HDPE container with white ribbed child resistant HDPE cap with a pulp liner in between the heat seal liner and inner cap.
TORASEMIDE BIOTECH 20:
100 tablets are packed in white HDPE container with white ribbed child resistant HDPE cap with a pulp liner in between the heat seal liner and inner cap.
All pack sizes and strengths may not necessarily be marketed at one time.

STORAGE INSTRUCTIONS:
Store at or below 25 °C. Keep tablets in container until required for use. Keep container well closed.
Keep all medicines out of reach of children.

REGISTRATION NUMBER:
TORASEMIDE BIOTECH 5: 45/18.1/1185
TORASEMIDE BIOTECH 10: 45/18.1/1186
TORASEMIDE BIOTECH 20: 45/18.1/1187

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: 26 November 2015
Date of latest revision as submitted: 05 April 2019

SKEDULERINGSTATUS:
S3

EIENDOMSNAAM EN DOSEERVORM:
TORASEMIDE BIOTECH 5 Tablette
TORASEMIDE BIOTECH 10 Tablette
TORASEMIDE BIOTECH 20 Tablette

SAMESTELLING:
TORASEMIDE BIOTECH 5: Elke tablet bevat 5,0 mg torasemied.
TORASEMIDE BIOTECH 10: Elke tablet bevat 10,0 mg torasemied.
TORASEMIDE BIOTECH 20: Elke tablet bevat 20,0 mg torasemied.
Ander bestanddele: Krospovidoon, laktose monohidraat, magnesiumstearaat, mikrokristallyn sellulose, povidoon.
Bevat suiker (laktose monohidraat)
Die 5 mg tablet bevat 79,00 mg, die 10 mg tablet bevat 158,00 mg en die 20 mg tablet bevat 316,00 mg laktose monohidraat, onderskeidelik.

FARMAKOLOGIESE KLASSIFIKASIE:
A 18.1 Diuretika.

FARMAKOLOGIESE WERKING:
Farmakodinamiese eienskappe
Torasemied is 'n lusdiuretikum. Dit inhibeer die aktiwiteit van die $Na^+K^+2Cl^-$ simpoteerder in die dik stygende been van Henlé, en inhibeer daardeur die herabsorpsie van renale natrium en chloried-ione. Torasemied het 'n verhoogde effek op die urinêre uitskeiding van Na^+ en Cl^- weens die $Na^+K^+2Cl^-$ simporteerder.
Torasemied verlaag bloeddruk aanvanklik deur die vermindering van plasma- en ekstrasellulêre vloeistofvolume; kardiale omset neem ook af. Mettertyd keer die kardiale uitset terug na normaal met 'n gepaardgaande afname in die perifêre weerstand.
Farmakokinetiese eienskappe
Torasemied word goed geabsorbeer na mondelinge toediening en word nie deur kos geaffekteer nie. Die bio-beskikbaarheid is ongeveer 80%. Die verspreidingsvolume (VolD is 0,14 to 0,19 ℓ per kg). Die proteïenbinding van torasemied is baie hoog en wissel tussen ongeveer 97 % tot meer as 99 %.
Torasemied word gemetaboliseer deur die hepatiese sitochroom P-450 stelsel na 5 metabolite. Die hoofmetaboliet, M5 is farmakologies onaktief. Torasemied is in die geheel verantwoordelik vir 80 % van die totale diuretiese aktiwiteit, terwyl die metaboliete M1 en M3 onderskeidelik verantwoordelik is vir 9 % en 11% van die diuretiese aktiwiteit.
Die eliminasie halfleeftyd van torasemied is 2,2 tot 3,8 uur; wanneer dit nie beïnvloed word deur matige nierversaking nie.
Die aanvang van diuretiese werking van torasemied vind binne 1 uur na orale toediening plaas. Die tyd na piek konsentrasie is 1 tot 2 uur. Tydsduur van die diuretiese aksie is 6 tot 8 uur.
Uitskeiding vind plaas deur middel van die niere, en 24 % word uitgeskei as die oorspronklike verbinding. Torasemied word nie suksesvol deur hemodialise verwyder nie.

INDIKASIES:
Essensiële hipertensie.
Edeem van kardiogene en hepatiese oorsprong.
Pulmonêre edeem weens akute kardiale ontoereikendheid.

KONTRAINDIKASIES:
• hipersensitiwiteit vir torasemied of enige van die ander bestanddele van TORASEMIDE BIOTECH
• nierversaking met afwesigheid van urienproduksie (anurie)
• hepatiese pre-koma en koma
• swangerskap en borsvoeding
• pasiënte met 'n bekende hipersensitiwiteit vir sulfonielureum
• hipovolemie
• hiponatremie, hipokalemie
• ernstige versteurings van mikturisie (bv prostaat hipertrofie)
TORASEMIDE BIOTECH moet nie gebruik word in kinders van 12 jaar of jonger nie.

WAARSKUWINGS en SPESIALE VOORSORGMAATREËLS:
TORASEMIDE BIOTECH moet nie gegee word aan pasiënte in 'n pre-komatose toestand wat verband hou met lewersirrose nie.
TORASEMIDE BIOTECH moet met sorg gebruik word in pasiënte met prostaathiperplasie of inkorting van mikturisie aangesien dit akute urienretensie kan ontketen.
Sorgvuldige monitering van koolhidraatmetabolisme word aanbeveel in pasiënte met diabetes mellitus of latente diabetes mellitus, aangesien 'n styging in bloedglukose kan voorkom.
Langtermyn behandeling met TORASEMIDE BIOTECH vereis gereelde monitering van die elektrolietbalans, glukose-, uriensuur- kreatinien- en lipiedvlakke.
Sorgvuldige monitering word vereis in pasiënte met 'n neiging om hiperurisemie en jig te ontwikkel.
Pasiënte met die seldsame oorerflike probleem van laktose- of glukose weerstandigheid, die gebrek aan glukose-galaktose wanabsorpsie (Lapp laktase), moet nie TORASEMIDE BIOTECH neem nie.
Uitwerking daarvan op die vermoë om te bestuur en die gebruik van masjinerie:
Individuele uiteenlopende reaksies kan paraatheid belemmer (b.v. die pasiënt se vermoë om 'n voertuig te bestuur en om masjinerie te gebruik). Dit geld veral wanneer daar met behandeling begin word, die omskakeling van 'n ander medikasie of met die begin van gebruik van mede-medikasie en in samewerking met alkohol.

INTERAKSIES:
Die uitwerking van antihipertensie medisyne mag vererger word wanneer dit in kombinasie met TORASEMIDE BIOTECH gebruik word.
Die opeenvolgende behandeling of begin van 'n nuwe gesamentlike-medikasie met 'n ACE-inhibeerder mag 'n oormatige daling in bloeddruk tot gevolg hê.
Die werking van antidiabetiese medisyne kan ook verminder word deur TORASEMIDE BIOTECH. Dosis aanpassings van hipoglisemiese medikasie mag nodig wees.
Gesamentlike en/of daaropvolgende toediening van TORASEMIDE BIOTECH en amfoterisien B parenteraal moet vermy word aangesien die potensiaal vir nefrotoksisiteit verhoog kan word, veral in die teenwoordigheid van nierfunksie inkorting.
Anti-inflammatoriese medisyne, NSAIDs, veral indometasien mag die natriuretiese werking van TORASEMIDE BIOTECH verminder.
Wanneer TORASEMIDE BIOTECH gelyktydig met digoksien gebruik word, mag 'n kalium en/of magnesium tekort die sensitiwiteit van die hartspier vir gebruik van digoksien verhoog.
Die gesamentlike gebruik van litium met TORASEMIDE BIOTECH kan die toksisiteit van litium vermeerder as gevolg van die verlaagde nieropruiming.
Probenesied kan die diuretiese werking van TORASEMIDE BIOTECH verminder.
Die risiko van hipokalemie kan verhoog word deur TORASEMIDE BIOTECH.
Die kali-diuretiese effek van mineraal- en glukokortikosteroïede en laksseermiddels kan verhoog word.
TORASEMIDE BIOTECH kan die skadelike gevolge van aminoglikosied antibiotika, sisplatien voorbereidings en kefalosporiene op die oor en niere versterk, veral teen hoë doserings.
Die werking van kuraar bevattende spierverslappers en van teofillien kan versterk word deur die gebruik van TORASEMIDE BIOTECH. TORASEMIDE BIOTECH kan die arteriële respons op pressor middels, bv. epinefrien (adrenalien) en norepinefrien (noradrenalien) verlaag.
Salisilaat-toksisiteit kan verhoog word by pasiënte wat hoë doserings salisilaat ontvang. As TORASEMIDE BIOTECH tesame met cholestiramien toegedien word kan die bio-beskikbaarheid en gevolglik, die effektiwiteit van TORASEMIDE BIOTECH verminder word.
Die antistollingseffekte van warfarien of heparien kan verminder word wanneer hierdie medisyne saam met TORASEMIDE BIOTECH gebruik word.
Die gesamentlike gebruik van simpatomimetika en TORASEMIDE BIOTECH mag die anhipertensiewe effekte daarvan verminder.

SWANGERSKAP EN BORSVOEDING:
Veiligheid en effektiwiteit van die gebruik in swanger vroue is nog nie vasgestel nie. Dit is ook nog nie bekend of TORASEMIDE BIOTECH in borsmelk vrygestel word nie. Sien KONTRAINDIKASIES.

DOSIS EN GEBRUIKSAANWYSINGS:
Essensiële hipertensie:
Behandeling word begin met 2,5 mg TORASEMIDE BIOTECH per day. Die gebruiklike onderhoudsdosis is 2,5 mg daagliks. As dit nie effektief genoeg is nie, kan die dosis tot 5,0 mg per dag verhoog word. Hoër dosering sal nie bloeddrukverlaging tot gevolg hê nie.
Edeem van kardiale, hepatiese en renale oorsprong:
Behandeling word begin met 5,0 mg TORASEMIDE BIOTECH per dag. Die gebruiklike onderhouds-dosis is 2,5 mg daagliks. As dit nie effektief genoeg is nie, kan die dosis verhoog word tot 20 mg per dag, afhangend van die erns van die siekte. In individuele gevalle is soveel as 40 mg TORASEMIDE BIOTECH per dag gegee. Orale toediening van TORASEMIDE BIOTECH kan met vloeistof op 'n leë maag of enige tyd soos verkies in ooreenstemming met 'n maaltyd geneem word.

NEWE EFFEKTE:
Immuunsisteem afwykings
Minder algemeen: Akute hipersensitiwiteitsreaksies (wat lewensgevaarlik kan wees).
Metabolisme- en voedingsafwykings
Minder algemeen: Versteurings van water- en elektrolietbalans, verlaagde kaliumvlakke, styging in die bloed ureum en kreatinien, stygings in Gamma-GT, verandering in die bloedglukose en lipiedmetabolisme en 'n styging in die uriensuur vlakke.
Senuweestelselafwykings
Frekwensie onbekend: Tekens van elektroliet en volume tekort soos hoofpyn, duiseligheid, gevoel van swakheid, verlies van eetlus en krampe, toestande van verwarring, parestesie.
Spysverteringskanaal afwykings
Algemeen: Simptome van die spysverteringskanaal (naarheid, braking, diarree, konstipasie).
Frekwensie onbekend: Droë mond
Renale- en nierafwykings
Frekwensie onbekend: In pasiënte met urinêre obstruksies bv. prostaat hipertrofie, in hierdie gevalle kan verhoogde urienproduksie lei tot urienretensie en dus lei tot uitsetting van die blaas.
Bloed- en limfsisteemafwykings
Minder algemeen: Behandeling met TORASEMIDE BIOTECH kan 'n afname in die korpuskulêre samestelling van die bloed (rooibloedselle, witbloedselle, plaatjies) veroorsaak.
Vaskulêre afwykings
Minder algemeen: Hipotensie.
Kardiale afwykings
Frekwensie onbekend: Tromboemboliese komplikasies en kardiale of serebrale iskemie of miokardiale infarksie.
Vel en subkutaneuse weefsel afwykings
Minder algemeen: Allergiese velreaksies, b.v. pruritus en eksanteem of fotosensitisasie.
Oogafwykings
Frekwensie onbekend: Visuele versteurings.
Oorafwykings
Minder algemeen: Ototoksisiteit ('n gesuis of gegons in die ore of gehoorverlies).

BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VIR DIE BEHANDELING DAARVAN:
In die geval van oordosering kan merkbaar verhoogde diurese voorkom met die gepaardgaande gevaar van vloeistof en elektrolietverlies wat kan lei tot slaperigheid en verwarring, hipotensie, sirkulatoriese ineenstorting en gastroïntestinale simptome. Geen spesifieke teemiddel is bekend nie. Simptome van oordosering verdwyn in die algemeen as medisyne dosis verminder of onttrek word en gelyktydige toediening van vloeistowwe en elektroliete plaasvind (moet gemonitor word). Behandeling is simptomaties en ondersteunend.

IDENTIFIKASIE:
TORASEMIDE BIOTECH 5: Wit tot naaswit, ovaalvormige, gedrukte tablette, gebosseleer, met '5' op een kant en gekeep aan die teenoorgestelde kant.
TORASEMIDE BIOTECH 10: Wit tot naaswit, ovaalvormige, gedrukte tablette, gebosseleer, met '10' op een kant en gekeep aan die teenoorgestelde kant.
TORASEMIDE BIOTECH 20: Wit tot naaswit, ovaalvormige, gedrukte tablette, gebosseleer, met '20' op een kant en gekeep aan die teenoorgestelde kant.

AANBIEDING:
TORASEMIDE BIOTECH 5 &10:
30 en 100 tablette is verpak in wit HDPE houers met wit geriffelde kinderbestande HDPE deksel met 'n pulpvoering tussen die hitte verseëlde voering en die binnekant van die deksel.
TORASEMIDE BIOTECH 20:
100 tablette is verpak in HDPE houers met wit geriffelde kinderbestande HDPE deksel met 'n pulpvoering tussen die hitte verseëlde voering en die binnekant van die deksel.
Al die verpakkingsgroottes en sterktes word nie noodwendig op een slag bemark nie.

BERGINGSINSTRUKSIES:
Berg by of benede 25 °C. Bewaar die tablette in die houer tot dit benodig word vir gebruik. Hou die houer dig toe.
Hou alle medisyne buite die bereik van kinders.

REGISTRASIENOMMERS:
TORASEMIDE BIOTECH 5: 45/18.1/1185
TORASEMIDE BIOTECH 10: 45/18.1/1186
TORASEMIDE BIOTECH 20: 45/18.1/1187

NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE REGISTRASIESERTIFIKAAT:
BIOTECH LABORATORIES (Edms) Bpk.
Grond vloer, Blok K Wes, Central Park
400 16de Weg, Randjespark, Midrand, 1685
Suid Afrika

DATUM VAN PUBLIKASIE VAN DIE VOUBILJET:
Datum van registrasie: 26 November 2015
Datum van die laaste hersiening soos ingedien: 05 April 2019.

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