

BACLOFEN 25 BIOTECH

Patient information leaflet

SCHEDULING STATUS:

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

BACLOFEN 25 BIOTECH: Each tablet contains 25 mg baclofen.

Please read this leaflet carefully before using BACLOFEN 25 BIOTECH tablets

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- BACLOFEN 25 BIOTECH has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. WHAT BACLOFEN 25 BIOTECH CONTAINS

The active substance is baclofen.

Dibasic Calcium Phosphate anhydrous, Colloidal silicon dioxide, Magnesium stearate, Microcrystalline cellulose, and Sodium carboxymethyl starch. BACLOFEN 25 BIOTECH containing 25 mg baclofen contains lactose, 60 mg, per tablet.

2. BACLOFEN 25 BIOTECH IS USED FOR

BACLOFEN 25 BIOTECH belongs to a group known as centrally acting muscle relaxants.

BACLOFEN 25 BIOTECH is used in adults to treat spasticity of the skeletal muscle due to multiple sclerosis, or spastic conditions occurring in spinal cord diseases of infectious, degenerative, traumatic, neoplastic or unknown etiology.

3. BEFORE YOU USE BACLOFEN 25 BIOTECH

Do not use BACLOFEN 25 BIOTECH:

- If you are hypersensitive (allergic) to Baclofen or any of the inactive ingredients of BACLOFEN 25 BIOTECH.
- If you have a galactose – lactose allergy or intolerance.
- If you suffer from epilepsy or seizures.
- If you have an active gastric or duodenal (stomach or small bowel) ulcer.
- If you have porphyria.
- If you are pregnant or are breastfeeding your baby.

Take special care with BACLOFEN 25 BIOTECH:

Special care should be taken in the following cases and you should inform your doctor if you suffer from any of the following:

- Hypertension and are currently on high blood pressure medication, as it can lower your blood pressure drastically.
 - The use of BACLOFEN 25 BIOTECH may lead to drowsiness, visual disturbances and impaired concentration which may be aggravated by the simultaneous intake of alcohol or central nervous system depressants agents.
 - If you ever had a stroke, you may not tolerate this treatment well.
 - If you have been diagnosed with Parkinson's disease and are on levodopa (alone or in combination with carbidopa) treatment. Your Parkinson's symptoms may get worse if you start taking BACLOFEN 25 BIOTECH.
 - If you suffer from psychiatric disorders, schizophrenia and depressive, manic disorders or confusional states, and treated with BACLOFEN 25 BIOTECH, your symptoms may also get worse and you should be monitored while receiving treatment.
 - If you are taking lithium for your depression.
 - If you have an active peptic ulcer or have a history of peptic ulcer.
 - If you suffer from cerebrovascular disease.
 - If you have diabetes (high blood sugar), as it can cause an increase in blood sugar.
 - If your kidneys, bladder or liver are not functioning properly.
 - BACLOFEN 25 BIOTECH should be used with caution in patients in whom spasticity is used to maintain posture or increase functional capacity.
- Whilst you are taking BACLOFEN 25 BIOTECH, your doctor may want to give you a check-up from time to time.

Taking BACLOFEN 25 BIOTECH with food and drink

You are advised NOT to drink alcohol with BACLOFEN 25 BIOTECH. Discuss with your doctor if you have any questions.

Swallow these tablets with water.

BACLOFEN 25 BIOTECH should be taken for as long as your doctor tells you to, it may be dangerous to stop treatment without their advice.

Pregnancy and breastfeeding:

The safe use of BACLOFEN 25 BIOTECH during pregnancy and breastfeeding has not been established.

You should not use BACLOFEN 25 BIOTECH if you are pregnant or breastfeeding your baby. Please consult your health care provider for advice.

Baclofen crosses the placenta and is distributed into breast milk.

Driving and using machinery:

BACLOFEN 25 BIOTECH can cause sleepiness, dizziness and low blood pressure. Do not drive a motor vehicle or operate machinery until you know how BACLOFEN 25 BIOTECH affects you.

Important information about some of the ingredients of BACLOFEN 25 BIOTECH

BACLOFEN 25 BIOTECH contains lactose (milk sugar) and should not be administered to patients with rare hereditary problems. or a history of lactose intolerance, Lapp lactose deficiency or glucose-galactose malabsorption.

Taking other medicines with BACLOFEN 25 BIOTECH

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines).

BACLOFEN 25 BIOTECH can cause interactions with the following medicines:

- Alcohol and other central nervous system (CNS) depressants, or sleeping tablets, as they may worsen the CNS effects of BACLOFEN 25 BIOTECH, especially sedation (making you feel sleepy) and should be avoided.
- Lithium (for bipolar disease or depression) as an increase in intensity of uncontrolled muscle action can occur, and should be avoided taking together.
- Tricyclic antidepressants (e.g. amitriptyline or imipramine), as you may experience an increase in muscle weakness.
- Medicines to treat high blood pressure (e.g. propranolol, nifedipine, captopril), as you may experience extreme lowering of blood pressure.
- NSAID's (anti-inflammatory pain medicine for example ibuprofen), as they may reduce BACLOFEN 25 BIOTECH excretion.
- if you are being treated for Parkinson's disease, as this combination can lead to mental confusion, hallucinations, headaches, nausea and agitation. Please consult your health care provider for advice.

4. HOW TO USE BACLOFEN 25 BIOTECH

Always take BACLOFEN 25 BIOTECH exactly as your doctor has instructed you. Do not take more or less tablets and do not take them more often than recommended. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of BACLOFEN 25 BIOTECH is too strong or too weak, talk to your health care provider.

Adults:

Treatment should as a rule be started with a dosage of 5 mg three times daily.

BACLOFEN 25 BIOTECH should be taken during meals with a little liquid. The usual BACLOFEN 25 BIOTECH dosage is 5 mg three times daily, gradually increasing up to 20 mg three times daily.

Your doctor might decide to increase your dosage depending on your specific need.

Patients with kidney problems:

Your health care provider may give you a lower dose (e.g. 5 mg daily).

Elderly patients:

Elderly patients are more likely to experience side effects; caution is advised and your health care provider will monitor your treatment carefully.

Children:

This presentation/dosage form is not recommended for children.

Do not stop taking the tablets suddenly as your symptoms may get worse or you may suffer confusion, hallucinations, changes in your mental state, fits or a fast heartbeat. Treatment with BACLOFEN 25 BIOTECH is usually reduced slowly and gradually over a period of 1-2 weeks.

If you take more BACLOFEN 25 BIOTECH than you should:

In the event of overdose you can experience seizures or coma. Consult your health care provider. If neither is available, seek help at the nearest hospital or poison control centre. There is no specific antidote. Take the empty container and any remaining tablets along with the patient so that the doctor can see what the patient has taken.

If you forget to take BACLOFEN 25 BIOTECH:

If you forget to take a dose, take it as soon as you remember.

Do not take a double or larger dose to make up for the forgotten individual doses. Continue to take the next tablet at the usual time.

Effects when treatment with BACLOFEN 25 BIOTECH is stopped:

Sudden withdrawal of BACLOFEN 25 BIOTECH after long term administration may cause continuous muscle tension and spasticity, severe high fever, altered mental status (feeling confused), and has progressed in rare instance to skeletal muscle tissue breakdown, multiple organ-system failure and death. Other withdrawal symptoms are hallucinations, anxiety and a heart rate that exceeds the normal range.

5. POSSIBLE SIDE EFFECTS

BACLOFEN 25 BIOTECH can have side effects. Not all side effects reported for BACLOFEN 25 BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BACLOFEN 25 BIOTECH, please consult your healthcare practitioner for advice.

If any of the following happens, stop taking BACLOFEN 25 BIOTECH and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious reaction to BACLOFEN 25 BIOTECH. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- chest pain
 - angina
 - changes in the way your heart beats, for example, if you notice it beating faster,
 - difficulty breathing
 - signs of recurrent infections such as fever or sore throat
 - less urine than is normal for you
 - yellowing of the skin and eyes, dark urine, and tiredness which may be symptoms of liver problems
- These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- drowsiness
 - nausea
 - sleepiness during the day
 - tiredness or weakness
 - insomnia
 - light-headedness
 - dizziness
 - confusion
 - headache
 - nightmares
 - difficulty breathing
 - sight disturbances
 - constipation or diarrhoea
 - dry mouth
 - Rash or itchy skin
- Less frequent side effects:*

- irregular and jerky movements
- increase in spastic symptoms
- shakiness in the arms and legs
- fits
- Euphoria (feeling very happy)
- uncontrolled eye movements
- difficulty in focusing
- hallucinations
- stomach pain
- itching
- impotence
- swelling of the ankles
- In-coordination
- depression
- stiff muscles
- ringing in the ears
- chest pain
- fast irregular heartbeat
- blood in the urine
- Erectile dysfunction
- Helplessness

The following side effects have been reported but the frequency is not known:

- forgetfulness
 - increased sweating
 - difficulty to urinate
 - weight gain or weight loss
 - increased urination during night time
- If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BACLOFEN 25 BIOTECH

Store at or below 25 °C and protect from light.

Do not store your tablets in the bathroom.

Keep the tablets in the original container until required for use.

Keep the container well closed.

KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Do not use after the expiry date printed on the carton or blister.

Return all unused medicine to your pharmacist

Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets)

7. PRESENTATION OF BACLOFEN 25 BIOTECH

BACLOFEN 25 BIOTECH: Securitainers, HDPE and cartons containing 30 and 100 tablets.

8. IDENTIFICATION OF BACLOFEN 25 BIOTECH

25 mg: 8 mm flat bevelled edge white tablet with score mark on one side and plain on other side.

9. REGISTRATION NUMBER

BACLOFEN 25 BIOTECH – W/2.10/237

10. NAME AND ADDRESS OF REGISTRATION HOLDER

BIOTECH LABORATORIES (PTY) LTD
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark, Midrand, 1685
Tel: (011) 848 3050

11. DATE OF PUBLICATION

23 June 2021

BACLOFEN 25 BIOTECH

Pasiëntinligtingsblad

SKEDULERING STATUS:

[S4]

HANDELSNAAM, STERKTE EN FARMASEUTIESE VORM

BACLOFEN 25 BIOTECH: Elke tablet bevat 25 mg baklofen.

Lees hierdie inligtingsblad aandagtig voordat u BACLOFEN 25 BIOTECH tablette gebruik.

- Bewaar hierdie inligtingsblad. Dit mag nodig wees om dit weer te lees.
- Indien u enige verdere vrae het, raadpleeg asseblief u dokter of u apteker.
- BACLOFEN 25 BIOTECH is vir u persoonlik voorgeskryf en moet nie met enige ander persone gedeel word nie. Dit mag skadelik wees, al is hul simptome dieselfde as wat u ervaar.

1. WAT BACLOFEN 25 BIOTECH BETEUT

Die aktiewe bestanddeel is baklofen.

Watervrye dibasiese kalsiumfosfaat, kolloïdale silikondioksied, magnesium stearaat, mikrokristallyne sellulose en natriumkarboksim-etielstysel BACLOFEN 25 BIOTECH met 25 mg baklofen bevat 60 mg laktose per tablet.

2. WAARVOOR BACLOFEN 25 BIOTECH GEBRUIK WORD

BACLOFEN 25 BIOTECH behoort aan 'n groep wat bekend staan as sentraalwerkende spierverslappers.

BACLOFEN 25 BIOTECH word gebruik in volwassenes om spastisiteit van die skeletspiere as gevolg van veelvuldige sklerose te behandel, of spastiese toestande wat voorkom met spinaalkoörd siektes van aansteeklike aard, degeneratiewe, traumatiese, neoplastiese of onbekende etiologieë.

3. VOORDAT U BACLOFEN 25 BIOTECH NEEM

Moet nie BACLOFEN 25 BIOTECH neem:

- Indien u hipersensitiwiteit (allergie) teen baklofen of enige van die onaktiewe bestanddele van BACLOFEN 25 BIOTECH het nie.
- Indien u galaktose-laktose allergieë of onverdraagsaamheid het nie
- Indien u aan epilepsie of konvulsies ly
- Indien u aktiewe gastriese of duodunale (maag of dunderm) ulkusse het nie
- As u aan porfirie ly
- As u swanger is of u baba borsvoed

Neem spesiale voorsorg met BACLOFEN 10/25 BIOTECH

Uiterste sorg moet geneem word in die volgende gevalle en u moet u dokter inlig indien u aan enige van die volgende toestande ly:

- Hoë bloeddruk en as u huidiglik op hoë bloeddruk medikasie is, omdat dit u bloeddruk drasties kan verlaag.
 - Die gebruik van BACLOFEN 25 BIOTECH kan lei tot lomerigheid, visuele versteurings en ingekorte konsentrasie wat vererger kan word deur die gelyktydige inname met alkohol of sentrale senuweestelsel onderdrukkende middels.
 - Indien u al 'n beroerte gehad het, mag u moontlike nie die middel goed verdra nie.
 - As u reeds met Parkinson siekte gediagnoseer is en met levodopa (alleen of in kombinasie met karbidopa) behandel word. U Parkinson's simptome kan vererger met gebruik van BACLOFEN 25 BIOTECH.
 - Indien u aan geestesversteurings ly, skisofrenie en depressie, maniese versteurings of toestande wat met verwarring gepaard gaan, en dan met BACLOFEN 25 BIOTECH behandel word, kan u simptome vererger en behoort u gereeld gemonitor te word terwyl u behandeling ontvang.
 - Indien u litium gebruik vir depressie.
 - As u 'n maagseer het of 'n geskiedenis van maagsere.
 - Indien u aan serebro-vaskulêre toestande ly.
 - As u diabetes (hoë bloedsuiker) het, aangesien 'n verhoging in bloedsuiker kan voorkom.
 - As u niere, blaas of lewer nie behoorlik funksioneer nie.
 - BACLOFEN 25 BIOTECH moet met versigtigheids gebruik word in pasiënte waar spastisiteit aangewend word om postuur of funksionaliteitsvermoë te verhoog.
- Tydens BACLOFEN 25 BIOTECH behandeling sal u dokter u van tyd tot tyd wil ondersoek.

Neem van BACLOFEN 25 BIOTECH met voedsel en vloeistof

Dit word NIE aanbeveel om alkohol te gebruik saam met BACLOFEN 25 BIOTECH NIE. Bespreek met u dokter indien u enige vrae daaroor het. Sluk tablette met water. BACLOFEN 25 BIOTECH behandeling moet so lank duur soos deur u dokter voorgeskryf. Dit kan gevaarlik wees om behandeling te staak sonder mediese advies.

Swangerskap en borsvoeding:

Die veiligheid van gebruik van BACLOFEN 25 BIOTECH gedurende swangerskap en borsvoeding is nog nie vasgestel nie. U moet nie BACLOFEN 25 BIOTECH gebruik indien u swanger is of u baba borsvoed nie.

Raadpleeg u gesondheidsorgverskaffer vir advies.

Baklofen kruis wel die plasenta en word in borsmelk versprei.

Bestuur en gebruik van masjinerie:

BACLOFEN 25 BIOTECH kan lomerigheid veroorsaak, duiseligheid en lae bloeddruk. Moet nie 'n motorvoertuig bestuur of masjinerie beheer totdat u weet hoe BACLOFEN 25 BIOTECH u affekteer nie.

Belangrike inligting rakende sommige van die bestanddele van BACLOFEN 25 BIOTECH

BACLOFEN 25 BIOTECH bevat laktose (melksuiker) en moet nie toegedien word aan pasiënte met rare oorerflikke probleme, of 'n geskiedenis van laktose onverdraagsaamheid nie, Lapp laktose ontoereikendheid of glukose-galaktose wanabsorpsie nie.

Neem van ander medikasie saam met BACLOFEN 25 BIOTECH

Lig altyd u gesondheidsorgverskaffer in as u ander medikasie neem, (Dit sluit komplimentêre en tradisionele medisyne in).

BACLOFEN 25 BIOTECH kan interaksies met die volgende medisyne veroorsaak:

- Alkohol en ander sentrale-senuweestelsel (SSS) onderdrukkers, of slaappille, omdat hul die SSS werking van BACLOFEN 25 BIOTECH kan vererger, veral sedasie (sodat u slaperig voel) en moet dus vermy word.
- Litium (vir bipolêre siekte of depressie) omdat 'n verhoging in intensiteit van onbeheerde spieraksie kan voorkom, en gesamentlike gebruik moet dus vermy word.
- Trisikliese antidepressante (bv. amitriptilien of imipramien) omdat u verhoogde spierswakheid kan ondervind.
- Medikasies wat hoë bloeddruk behandel (bv. propranolol, nifedipien, kaptopriël), omdat u erge verlaging in bloeddruk mag ondervind.
- NSAID's (anti-inflammatoriese pyn medikasie byvoorbeeld ibuprofen), omdat dit die uitwerking van BACLOFEN 25 BIOTECH kan verhandel.
- Indien u vir Parkinson siekte behandel word, omdat die kombinasie ken lei tot verwarring, hallusinasies, hoofpyn, naarheid en agitatie.
- Raadpleeg u gesondheidsorgverskaffer vir advies.

4. HOE OM BACLOFEN 25 BIOTECH TE GEBRUIK

Neem altyd BACLOFEN 25 BIOTECH presies soos deur u dokter voorgeskryf. Moet nie meer of minder tablette of meer gereeld neem as wat aanbeveel is nie. U moet met u dokter of apteker raadpleeg indien u onseker is.

Indien u voel dat die effek van BACLOFEN 25 BIOTECH te sterk of te swak vir u is, moet u met u gesondheidsorgverskaffer raadpleeg.

Volwassenes:

Behandeling moet as 'n reël begin met 'n dosering van 5 mg drie maal per dag.

BACLOFEN 25 BIOTECH moet gedurende maaltye geneem word met 'n klein hoeveelhede water.

Die normale BACLOFEN 25 BIOTECH dosering is 5 mg drie maal per dag, geleidelike verhoging tot en met 20 mg drie keer per dag.

U dokter mag besluit om die dosering te verhoog afhangend van u spesifieke behoeftes.

Pasiënte met nierprobleme:

U gesondheidsorgverskaffer kan 'n laer dosering aanbeveel (bv. 5 mg per dag).

Bejaarde pasiënte:

Bejaarde pasiënte is meer geneig tot newe-effekte, daarom word versigtigheid aanbeveel en u gesondheidsorgverskaffer sal u behandeling noukeurig monitor.

Kinders:

Hierdie aanbevelings- /doseervorm word nie aanbeveel vir kinders nie. Moet nie skielik ophou om tablette te neem nie, omdat u simptome erger mag word en u verwarring, hallusinasies, verandering in geestestoestand, aanvalle of vinnige hartklop kan ervaar.

Behandeling met BACLOFEN 25 BIOTECH moet geleidelik en geleidelik oor 'n periode van 1 – 2 weke verminder word.

Indien u meer BACLOFEN 25 BIOTECH neem as voorgeskryf:

In die geval van oordosering kan u aanvalle of koma ervaar. Raadpleeg u gesondheidsorgverskaffer. Indien hul nie beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum. Daar is geen spesifieke teenmiddel nie.

Neem die leë houër en enige oorblywende tablette saam met die pasiënt, sodat die dokter kan sien wat die pasiënt geneem het.

Indien u vergeet om u BACLOFEN 25 BIOTECH te neem:

Indien u vergeet het om 'n dosis te neem, neem dit sodra u onthou. Moet nie dubbele of groter dosisse neem om op te maak vir vergeete individuele dosisse nie. Gaan voort met die volgende tablet op die gewone tyd.

Effekte wanneer behandeling met BACLOFEN 25 BIOTECH gestaak word:

Skielike ontrekking van BACLOFEN 25 BIOTECH na langtermyn toediening kan aanhoudende spierspanning en spastisiteit, erge hoë koors, veranderde geestestoestand (gevoel van verwarring) veroorsaak en kan in rare gevalle vorder tot die afbreek van skeletspierweefsel, veelvuldige orgaan-sistemoersaking en sterfte. Ander ontrekkingsimptome is hallusinasies, angs en vinnige hartklop wat die normale perke oorskry.

5. MOONTLIKE NEWE-EFFEKTE

BACLOFEN 25 BIOTECH kan wel newe-effekte hê. Nie alle newe-effekte al waargeneem vir BACLOFEN 25 BIOTECH is ingesluit in hierdie inligtingsblad nie.

Indien u algemene gesondheid verswak of as u enige ongewone effekte ervaar tydens behandeling met BACLOFEN 25 BIOTECH, moet met u gesondheidsorgverskaffer geraadpleeg word vir advies.

Indien enige van die volgende gebeur, moet u onmiddellik behandeling staak en u dokter inlig of na die noodgevall afdeling van die naaste hospitaal gaan:

- Swelling van die hande, voete, enkels, gesig, lippe, mond of keel, wat sluk of asemhaling bemoeilik
- Veluitslag of gejeuk
- Floute

Hierdie is almal ernstige newe-effekte. Indien u enige van die newe-effekte ervaar het, u moontlike 'n ernstige reaksie teenoor BACLOFEN 25 BIOTECH. U mag dringend mediese aandag benodig.

Lig u dokter onmiddelik in of gaan na die noodgevall afdeling by die naaste hospitaal, as u enige van die volgende ervaar:

- Borspyn
- Angina
- Verandering in die manier wat u hart klop, bv. as u opmerk dat dit vinniger klop
- Moeilike asemhaling
- Aanduidings van herhaalde infeksie soos koors en seer keel,
- Minder urine as wat normaal is vir u,
- Vergelting van velkleur en of die oë, donker urine, moegheid wat simptome van lewer probleme aandui.

Hierdie is almal ernstige newe-effekte. U mag dringende mediese aandag benodig.

Lig u dokter in as u enige van die volgende ervaar:

Algemene newe-effekte:

- Slaperigheid
- Naarheid
- Slaperigheid gedurende die dag
- Moegheid of swakheid
- Slaaploosheid
- Lighoofdigheid
- Duiseligheid
- Verwarring
- Hoofpyn
- Nagmerries
- Moeilike asemhaling
- Visie versteurings
- Hardlywigheid of diarree
- Droë mond
- Uitslag of gejeuk

Minder algemene newe-effekte:

- Onreëlmatige en rukkerige bewegings
- Verhoging van spastiese simptome
- Bewegigheid in die arms of bene
- Aanvalle/Stuiprekkings
- Euforie (voel baie gelukkig)
- Onbeheerde oogbewegings
- Moeilike fokus
- Hallusinasies
- Maagpyn
- Jeuk
- Impotensie
- Swelling van die enkels
- Swak ko-ordinasie
- Depressie
- Stywe spiere
- Gesuis in die ore
- Borskaspyn
- Vinnige onreëlmatige hartklop
- Bloed in die urine
- Erektiele disfunksie
- Hulpeloosheid

Die volgende newe-effekte is al aangemeld, maar die frekwensie daarvan is onbekend:

- Vergeetagtigheid
 - Verhoogde sweet
 - Probleme om te urineer
 - Gewigsverlies of toename
 - Verhoogde urinering gedurende die nag
- Lig u dokter of apteker in, indien u enige newe-effekte wat nie in hierdie inligtingsblad benoem word nie, ervaar.

6. BEWARING EN BERGING VAN BACLOFEN 25 BIOTECH

Bewaar teen of benede 25 °C en beskerm teen lig.

Moet nie die tablette in u badkamer berg nie.

Bewaar die tablette in die oorspronklike houër tot benodig vir gebruik.

HOU ALLE MEDIÏSYNE BUITE DIE BEREIK VAN KINDERS.

Moet nie gebruik na die vervaldatum wat op die houër aangedui is nie.

Besorg alle ongebruikte medisyne terug aan u apteker.

Moet nie van ongebruikte medisyne in afvoer of rioolstelsels ontslae raak nie (bv. toilette).

7. AANBIEDING VAN BACLOFEN 25 BIOTECH

BACLOFEN 25 BIOTECH: Veiligheidshouers, HDPE en kartonne wat 30 en 100 tablette bevat.

8. IDENTIFIKASIE VAN BACLOFEN 25 BIOTECH

25 mg; 8 mm plat wit tablet met 'n skuins rand, 'n keepmerk aan een kant, en plat aan die omkeerkant.

9. REGISTRASIE NOMMER

BACLOFEN 25 BIOTECH – W/2.10/237

10. NAAM EN ADRES VAN REGISTRASIE HOUER

BIOTECH LABORATORIES (EDMS) BPK
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400 16^{de} Weg, Randjespark, Midrand, 1685
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11. DATE OF PUBLICATION

23 Junie 2021