

BIO CIMETIDINE

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

53

BIO CIMETIDINE 200, 200 mg film-coated tablets.
BIO CIMETIDINE 400, 400 mg film-coated tablets.
Cimetidine
Sugar free

Read all of this leaflet carefully before you are given BIO CIMETIDINE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- BIO CIMETIDINE 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.

WHAT IS IN THIS LEAFLET

1. What BIO CIMETIDINE is and what it is used for
2. What you need to know before you take BIO CIMETIDINE
3. How to take BIO CIMETIDINE
4. Possible side effects
5. How to store BIO CIMETIDINE
6. Contents of the pack and other information

1. What BIO CIMETIDINE is and what it is used for

BIO CIMETIDINE is an antacid and is used for the treatment of duodenal and benign gastric ulceration (ulcers in the first part of the small intestine and in the stomach) and peptic oesophagitis, recurrent ulceration, stomal ulceration (ulceration near the opening between the stomach and the small intestine) and other conditions where reduction of gastric acid secretion has been shown to be beneficial as well as maintenance therapy for periods of up to one year in those patients with recurrence of duodenal ulceration after short-term therapy.

BIO CIMETIDINE is indicated in the management of those patients who are at high risk for bleeding of the upper gastrointestinal tract due to liver failure and treatment with medicines which lowers the body's resistance to disease, following kidney transplant. Management of pathological hypersecretion such as Zollinger-Ellison syndrome, systemic mastocytosis, multiple endocrine adenomas and erosive gastro-oesophageal reflux disease (GORD).

2. What you need to know before you take BIO CIMETIDINE

Do not take BIO CIMETIDINE:

- If you are hypersensitive (allergic) to cimetidine or any of the other ingredients of BIO CIMETIDINE (listed in section 6).
- If you are pregnant or breastfeeding your baby (see PREGNANCY AND BREASTFEEDING).

Warnings and precautions

Tell your doctor if any of the following applies to you:

- If you have reduced renal function.
- If you are a middle-aged or elderly person, with new or recently changed indigestion symptoms (e.g. stomach pain or discomfort, heartburn).
- If you have a history of peptic ulcer, or if you are taking a non-steroidal anti-inflammatory medicine (NSAID) e.g. aspirin, ibuprofen, naproxen, diclofenac.
- If you are taking medicines, or you have an illness, that could cause a fall in blood cell count.

Children and adolescents

The use of BIO CIMETIDINE in children cannot be recommended as safety and/or efficacy has not been established.

Other medicines and BIO CIMETIDINE

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

Tell your doctor if you are taking any of the following medicines:

- Immunodepressants (ciclosporin).
 - Heart medicines (e.g. nifedipine, diltiazem, lignocaine (lidocaine), metoprolol, procarinamide).
 - Anticonvulsants, to prevent fits (e.g. phenytoin).
 - Suxamethonium (used for relaxing the muscle).
 - Bronchodilators for breathing difficulties (e.g. theophylline).
 - Antidepressants (e.g. amitriptyline).
 - Antidiabetics (lowers glucose levels in the blood) (e.g. glipizide or metformin).
 - Antifungals (used to treat fungal infections) (e.g. ketoconazole, itraconazole or posaconazole).
 - Anti-cancer medicines (treatment of cancer or tumour) (e.g. carbustine, fluorouracil, epirubicin, or therapies such as radiation).
 - Strong pain killers (e.g. morphine).
 - Tacrolimus for the prevention of rejection following organ transplant.
 - Antiretroviral medicines (used to treat HIV/AIDS) (e.g. atazanavir).
 - Anticoagulants to thin your blood (e.g. warfarin).
- When administered with BIO CIMETIDINE, a reduction in the dosage of these medicines may be needed. If concurrent administration of warfarin and BIO CIMETIDINE is necessary, your doctor will closely monitor the prothrombin time (the time taken for blood clotting to occur).

BIO CIMETIDINE with food and drink alcohol

The day time doses should be taken with food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking BIO CIMETIDINE. Safety in pregnancy and breastfeeding has not been established. You should not take BIO CIMETIDINE if you are pregnant or breastfeeding your baby.

Driving and using machines

Confusion, headache and dizziness have been reported with BIO CIMETIDINE. You should not drive or use machines until you know how BIO CIMETIDINE affects your ability to do so safely.

BIO CIMETIDINE contains sodium

BIO CIMETIDINE contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially sodium-free.

3. How to take BIO CIMETIDINE

Do not share medicines prescribed for you with any other person. Always take BIO CIMETIDINE exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. BIO CIMETIDINE may be given by mouth or the nasogastric (passed through the nose into the stomach) route, and the total daily dose should not exceed 2,4 g. When BIO CIMETIDINE is given orally, the daytime doses should be taken with meals.

Duodenal and gastric ulcers

A single dose of 800 mg daily taken at bedtime, for 4 weeks in the case of a duodenal ulcer, and 6 weeks for a gastric ulcer. Where appropriate, a maintenance dose of 400 mg at bedtime or 200 mg twice daily should be taken for a period up to a year.

Oesophageal reflux

A dose of 400 mg four times daily (with meals and at bedtime) for 4-8 weeks is recommended.

Zollinger-Ellison syndrome

A dose of 400 mg four times daily (with meals and at bedtime) for 4-8 weeks is recommended. This dose can be increased to a maximum of 2,4 g per day, if necessary.

Maintenance treatment: Prophylaxis of recurrent ulcer

400 mg at bedtime or increase to 400 mg twice a day, if necessary for up to one year. Your doctor will tell you how long your treatment with BIO CIMETIDINE will last.

If you have the impression that the effect of BIO CIMETIDINE is too strong or too weak, tell your doctor or pharmacist.

If you take more BIO CIMETIDINE than you should
In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take BIO CIMETIDINE

If you have forgotten to take a dose, leave out that dose completely if it is almost time for your next dose. Take your next dose at the normal time. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

BIO CIMETIDINE can have side effects. Not all side effects reported for BIO CIMETIDINE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking BIO CIMETIDINE, please consult your doctor, pharmacist or other health care provider for advice.

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

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

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to BIO CIMETIDINE. 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:

- yellowing of the skin and eyes, also called jaundice,
- a rare type of anaemia in which the red and white blood cells and platelets are all reduced in number (symptoms might include tiredness, being short of breath), looking pale, frequent infections, bruising more easily or nose bleeds).

Tell your doctor if you notice any of the following:

Frequent side effects:

- Aching muscles and/or joints
- tiredness,
- diarrhoea,
- headache,
- dizziness.

Less frequent side effects:

- anaphylaxis,
- increase in heartrate,
- slow or irregular heartbeat,
- hair loss,
- redness of the skin because of contact with irritating substance,
- kidney problems (symptoms may include changes in the amount of urine passed and its colour, nausea, vomiting, confusion, fever and rash),
- joint pain,
- fever,
- confusion,
- trouble getting or keeping an erection (impotence),
- breast enlargement in men,
- nipple discharge,
- feelings of sadness, depression,
- hallucinations – seeing/feeling/hearing things that are not there,
- inflammation of the pancreas (sudden onset of abdominal pain, nausea and vomiting).
- liver disease with nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, and dark coloured urine.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the *"6.04 Adverse Drug Reaction Reporting Form"*; found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of BIO CIMETIDINE.

5. How to store BIO CIMETIDINE

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Store at or below 25 °C, protected from light.
- Do not store in bathrooms.
- Do not use after the expiry date stated on the label and carton.
- Take any expired medicine or medicine not used to your closest pharmacy for destruction.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What BIO CIMETIDINE contains

The active substance is cimetidine 200 mg per film-coated tablet or cimetidine 400 mg per film-coated tablet.

The other ingredients are colloidal silicone dioxide, hydroxypropyl methylcellulose, magnesium stearate, microcrystalline cellulose, macrogol/polyethylene glycol, povidone K25, sodium lauryl sulphate, sodium starch glycolate, starch, purified talcum, titanium dioxide.

What BIO CIMETIDINE looks like and contents of the pack

BIO CIMETIDINE 200 tablets are white, round shaped, biconvex, film coated tablets with no signs of cracking, chipping or peeling.
BIO CIMETIDINE 400 tablets are white, bar shaped, biconvex film coated tablets with no signs of cracking, chipping or peeling.

BIO CIMETIDINE tablets are available in:

BLISTER PACKS (10 or 14 tablets per strip)
Blister strips with clear, colourless PVC-coated PVC moulded to accept one tablet per pocket and sealed with soft, matte, silver, printed aluminium foil. Strips are packed into cartons with a professional information.
BIO CIMETIDINE 200 pack sizes included 20, 60 and 150 tablets.
BIO CIMETIDINE 400 pack sizes included 14, 56, 60 and 500 tablets.

SECURITAINERS

Securitainer (polypropylene) containing tablets, foam insert and professional information. Sealed with a securitainer snap-on cap (polyethylene) and labelled with a glossy adhesive printed label.
BIO CIMETIDINE 200 pack sizes included 60 and 150 tablets.
BIO CIMETIDINE 400 pack sizes included 60 and 500 tablets.

HDPE CONTAINERS

White opaque HDPE Container with white opaque screw cap and induction sealing wad.
BIO CIMETIDINE 200 pack sizes included 60 and 150 tablets.
BIO CIMETIDINE 400 pack sizes included 60 and 500 tablets.

Holder of certificate of registration

Biotech Laboratories (Pty) Ltd
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400 16th Road, Randjespark, Midrand, 1685
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Tel nr.: 011 848 3050

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Registration number

BIO CIMETIDINE 200: 31/11.4.3/0679
BIO CIMETIDINE 400: 31/11.4.3/0680

Botswana: Bio Cimetidine 200 Reg. No. BOT0600855 Bio Cimetidine 400 Reg. No. BOT0600856	S2 S2
Zimbabwe: Bio Cimetidine 200 Reg. No. 96/16.7/3089 Bio Cimetidine 400 Reg. No. 96/16.7/3090	PP10 PP10
Namibia: Bio Cimetidine 200 Reg. No. 12/11.4.3/0011 Bio Cimetidine 400 Reg. No. 12/11.4.3/0012	NS2 NS2

BIO CIMETIDINE

PASIENTINLIGTINGSBLAD

SKEDULERINGSSTATUS

[53]

BIO CIMETIDINE 200, 200 mg filmbedekte tablette
BIO CIMETIDINE 400, 400 mg filmbedekte tablette
Simetidien
Suikervry

Lees hierdie hele blad noukeurig deur voordat u BIO CIMETIDINE 200 drink.

- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog vree het, moet u asseblief vir u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer vra.
- BIO CIMETIDINE is vir u persoonlik voorgeskryf en u moet nie u medisyne vir ander mense gee nie. Dit kan hulle skaad, selfs al is hulle simptome dieselfde as u s'n.

WAT IN HIERDIE BLAD IS

- Wat BIO CIMETIDINE is en waarvoor dit gebruik word
- Wat u moet weet voordat u BIO CIMETIDINE drink
- Hoe om BIO CIMETIDINE te drink
- Moontlike newe-effekte
- Hoe om BIO CIMETIDINE te bêre
- Inhoud van die pak en ander inligting

1. Wat BIO CIMETIDINE is en waarvoor dit gebruik word

BIO CIMETIDINE is 'n teenuurmiddel en word gebruik vir die behandeling van duodenale en goedaardige maagsere (sere in die eerste deel van die dunderm en in die maag) en peptiese esofagitis, herhalende ulserasie, stomale ulserasie (sere naby die opening tussen die maag en die dunderm) en ander toestande waar minder afskedling van maagsuur as voordelig getoon is, sowel as onderhoudsterapie vir periodes van tot een jaar in daardie pasiënte met 'n herhaling van duodenale ulserasie na korttermynbehandeling. BIO CIMETIDINE is aangedui vir die behandeling van daardie pasiënte wat vanweë lewerversaking 'n hoë risiko vir bloeding in die boonste deel van die spysverteringskanaal het, en behandeling met medisyne wat die liggaam se weerstand teen siektes verlaag, na nieroorplanting. Bestuur van patologiese hiperafskeiding soos Zollinger-Ellison-sindroom, sistemiese mastositose, meervoudige endokriene adenome en erosiewe gastro-esofageale refluxsiekte (GERS).

2. Wat u moet weet voordat u BIO CIMETIDINE drink

Moenie BIO CIMETIDINE drink nie:

- as u hipersensitief (allergies) vir simetidien of vir enige van die ander bestanddele (gelys in afdeling 6) van BIO CIMETIDINE is.
- as u swanger is of u baba borsvoed (kyk Swangerskap en borsvoeding).

Waarskuyings en voorsorgmaatreëls

Sê vir u dokter indien enige van die volgende op u van toepassing is:

- As u swak nierfunksie het
- As u 'n middeljarige of bejaarde persoon is, met nuwe of onlangs veranderde spysverteringsimptome (bv. maagpyn of -ongemak, soibrand)
- As u 'n geskiedenis van peptiese ulkus het, of as u 'n nie-steroid anti-inflammatoriese middel (NSAIM) gebruik, bv. aspirien, ibuprofen, naprokseen, diklofenak
- As u medisyne gebruik, of u het 'n siekte, wat 'n daling in bloedseltelling veroorsaak

Kinders en adolessente

Die gebruik van BIO CIMETIDINE vir kinders word nie aanbeveel nie omdat die veiligheid en/of effektiwiteit nie bepaal is nie.

Ander medisyne en BIO CIMETIDINE

Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).

Sê vir u dokter as u enige van die volgende middels gebruik:

- Immuunonderdrukkers (siklosporien)
- Hartmedisyne (bv. nifedipien, diltiasem, lignokaïen/lidokaïen, metoprolol, prokaiënamied)
- Antikonvulsante, om aanvalle te voorkom (bv. fenitoïen)
- Suksametonium (om die spiere te laat ontspan)
- Brongodiatore vir asemhalingsprobleme (bv. teofilien)
- Trisikliese verbindings (bv. amitriptilien)
- Antidiabetika (verlaag glukosevlakke in die bloed) (bv. glipisied of metformien)
- Antifungusmiddels (om swaminfeksies te behandel) (bv. ketokonasool, itrakonasool, of posakonasool)
- Antikankermidisyne (behandeling van kanker of gewas) (bv. karmustien, fluoorurasiel, epirubisien of behandeling soos bestraling)
- Sterk pynstillers (bv. morfine)
- Takrolimus vir die voorkoming van verwerping na orgaanorplanting
- Antiretrovirale medisyne (om MIV/VIGS te behandel) (bv. atasanavir)
- Antikoagulantse om bloed dun te maak (bv. warfarin)

As dit saam met BIO CIMETIDINE gegee word, kan 'n verlaging in die dosis van hierdie medisyne nodig wees. As gelyktydige toediening van warfarien en BIO CIMETIDINE nodig is, sal u dokter die protrombientyd (die tyd wat dit bloed neem om te stol) noukeurig monitor.

BIO CIMETIDINE saam met voedsel en drank

Die dosis in die dag moet tydens etes gedrink word.

Swangerskap en borsvoeding

As u swanger is of borsvoed, dink dat u dalk swanger kan wees of beplan om 'n baba te hê, moet u u dokter, apteker of ander gesondheidspraktisyn om advies raadpleeg voordat u BIO CIMETIDINE drink. Die veiligheid tydens swangerskap en borsvoeding is nie bepaal nie. U moet nie BIO CIMETIDINE drink as u swanger is of u baba borsvoed nie.

Motorbestuur en gebruik van masjinerie

Verwardheid, hoofpyn en duiseligheid is met BIO CIMETIDINE aangemeld. U moet nie 'n voertuig bestuur of masjine gebruik nie totdat u weet hoe BIO CIMETIDINE u vermoë om dit veilig te doen, beïnvloed nie.

BIO CIMETIDINE bevat natrium

BIO CIMETIDINE bevat minder as 1 mmol (23 mg) natrium per ml, en is dus inderwaarheid natriumvry.

3. Hoe om BIO CIMETIDINE te drink

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie. Drink BIO CIMETIDINE altyd presies soos wat u dokter vir u gesê het. Raadpleeg u dokter of apteker as u nie seker is nie. BIO CIMETIDINE kan per mond of nasogastriese roete (deur die neus in die maag in) gegee word, en die totale daaglikse dosis moet nie 2,4 g oorskry nie. Wanneer BIO CIMETIDINE oral gegee word, moet die dosisse in die dag tydens etes gedrink word.

Duodenale en maagsere

'n Enkele dosis van 800 mg daaglik voor slaaptyd gedrink, vir 4 weke in die geval van 'n duodenale ulkus, en 6 weke vir 'n maagseer. Waar toepaslik, moet 'n instandhoudingsdosis van 400 mg voor slaaptyd of 200 mg twee keer per dag vir 'n tydperk tot 'n jaar gedrink word.

Esofageale reflux

'n Dosis van 400 mg vier keer per dag (met etes en met slaaptyd) vir 4-8 weke word aanbeveel.

Zollinger-Ellisonsindroom

'n Dosis van 400 mg vier keer per dag (met etes en met slaaptyd) vir 4-8 weke word aanbeveel. Hierdie dosis kan, indien nodig tot 'n maksimum van 2,4 g per dag verhoog word.

Onderhoudsbehandeling: Profylakse van herhalende ulkus

400 mg voor slaaptyd of verhoog, indien nodig, tot 400 mg twee keer per dag vir tot een jaar.

U dokter sal vir u 'n sê hoe lank u behandeling met BIO CIMETIDINE sal duur. Sê vir u dokter of apteker as u die indruk het dat die effek van BIO CIMETIDINE te sterk of te swak is.

As u meer BIO CIMETIDINE gedrink het as wat u moet

Raadpleeg u dokter of apteker in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om BIO CIMETIDINE te drink

As u vergeet het 'n dosis te drink, los daardie dosis heeltemal, behalwe as dit bykans tyd vir die volgende dosis is. Drink u volgende dosis op die gewone tyd. Moenie 'n dubbele dosis drink om vir vergete individuele dosisse op te maak nie.

4. Moontlike newe-effekte

BIO CIMETIDINE kan newe-effekte hê.

Nie al die newe-effekte wat vir BIO CIMETIDINE aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe-effekte ervaar terwyl u BIO CIMETIDINE gebruik, moet u u dokter, apteker of ander gesondheidskundige om advies raadpleeg.

Indien enige van die volgende voorkom, moet u ophou om BIO CIMETIDINE te drink en onmiddellik vir u dokter sê of na die ongevalle-afdeling van u naaste hospitaal gaan:

- swelling van die hande, voete, enkels, gesig, lippe, mond of keel wat probleme met sluk of asemhaling kan veroorsaak
 - veluitslag of jeuk
 - floutes of stadige en/of onreëlmatige hartklop
- Hierdie is almal baie ernstige newe-effekte. As u dit ervaar, kan dit wees dat u 'n ernstige allergiese reaksie op BIO CIMETIDINE het. Dit mag wees dat u dringende mediese aandag of hospitalisasie nodig het.

Sê dadelik vir u dokter of gaan na die ongevalle-afdeling van u naaste hospitaal as u enige van die volgende opmerk:

- geel vlekuring van die vel of oë, ook geelsgu genoom
- 'n seldsame tipe bloedarmoede waarin die rooi- en witbloedselle en bloedplaatjies almal minder word (simptome kan moegheid, kortasemheid, bleep voorkoms, aanhoudende infeksies, makliker kneusing of neusbloeding insluit)

Sê vir u dokter as u enige van die volgende opmerk:

Newe-effekte wat dikwels voorkom:

- seer spiere en/of gewigte
 - moegheid
 - diarree
 - hoofpyn
 - duiseligheid
- Newe-effekte wat minder dikwels voorkom:*
- anafлакse
 - vinnige hartklop
 - stadige of onreëlmatige hartklop
 - haarverlies
 - rooiheid van die vel as gevolg van kontak met 'n irriterende stof
 - nierprobleme (simptome kan veranderinge in die hoeveelhed urien wat gelaat word en die kleur daarvan, naarheid, braking, verwardheid, koors en uitslag insluit)
 - gewrigspyn
 - koors
 - verwardheid
 - probleme om te 'n ereksie te kry of te behou (impotensie)
 - vergoting van die borste in mans
 - afskeduit uit die tepels
 - intense gevoel van hartseer, depressie
 - hallusinasies - sien/voel/hoor goed wat nie daar is nie
 - ontsteking van die pankreas (skielike pyn in die buik, naarheid en braking)
 - lewersiekte met naarheid, braking, aptyverlies, algemene ongesteldheid, koors, jeuk, geel vlekuring van die vel en oë, donker gekleurde urien
- As u enige newe-effekte opmerk wat nie in hierdie blad genoem word nie, moet u u dokter of apteker asseblief in kennis stel.

Aanmeld van newe-effekte

Praat met u dokter of apteker as u newe-effekte ervaar. U kan newe-effekte ook by SAROGP ("SAHPRA") aanmeld via die vorm "*6.04 Adverse Drug Reaction Reporting Form*" wat aanlyn by SAHPRA se publikasies gekry kan word: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van BIO CIMETIDINE te gee.

5. Hoe om BIO CIMETIDINE te bêre

- HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
- Bêre by of onder 25 °C, beskerm teen lig.
- Moenie in badkamers bêre nie.
- U moet dit nie na die vervaldatum op die etiket en karton gebruik nie.
- Neem alle medisyne wat verval het of medisyne wat nie gebruik word nie vir vernietiging na u naaste apteek.
- Ongebruikte medisyne moet nie in dreinerings- of rioolstelsels (bv. toilette) gegooi word nie.

6. Inhoud van die pak en ander inligting

Wat BIO CIMETIDINE bevat

Die aktiewe bestanddeel is 200 mg simetidien per filmbedekte tablet of 400 mg simetidien per filmbedekte tablet. Die ander bestanddele is kolloïdale silindoksiëd, hidroksiopropielmetiësel-lulose, magnesiumstearaat, mikrokristallyne sellulose, makrogol/ poliëtleenglikol, povidoon K25, natriumlouresulfaat, natriumstyselglukolaat, stysel, gesuiwerde talk, titaandioksied.

Hoe BIO CIMETIDINE lyk en die inhoud van die pakkie

BIO CIMETIDINE 200 tablette is wit, ronde, bikonvekse, filmbedekte tablette, met geen tekens van krake, versplintering of afdopping nie. BIO CIMETIDINE 400 tablette is wit, staafvormige, bikonvekse, filmbedekte tablette, met geen tekens van krake, versplintering of afdopping nie.

BIO CIMETIDINE-tablette is beskikbaar in:

STULPSTROKE (10 of 14 tablette per stulpstrok)

Stulpstrok met helder, kleurlose PVDC bedekte PVC gevorm om een tablet per stulp te hou en verseël met sagte, silwer, bedrukte aluminiumfoelie met matfwerking. Stroke is met 'n professionele inligtingsblad in kartonne verpak. BIO CIMETIDINE 200 pakgroottes het 20, 60 en 150 tablette. BIO CIMETIDINE 400 pakgroottes het 14, 56, 60 en 500 tablette.

VEILIGHEIDSHOUERS

Veiligheidsouers (polipropileen) wat tablette, skuiminsedel en professionele inligting bevat. Verseël met 'n beveiligende opknipdop (poliëtleëlen) en gemerk met 'n bedrukte, glansende kleefetiket. BIO CIMETIDINE 200 pakgroottes het 60 en 150 tablette. BIO CIMETIDINE 400 pakgroottes het 60 en 500 tablette.

HDPE-HOUERS:

Wit ondeursigtige HDPE-houer met wit ondeursigtige skroefdop en induksie-seëlpluis.

BIO CIMETIDINE 200 pakgroottes het 60 en 150 tablette. BIO CIMETIDINE 400 pakgroottes het 60 en 500 tablette.

Houer van die registrasiesertifikaat

Biotech Laboratories (Edms) Bpk
Grondvloer, Blok K Wes, Central Park
16th Weg 400, Randjespark, Midrand 1685
Suid-Afrika
Tel nr.: 011 848 3050

Hierdie blad is laas hersien op

Augustus 2021

Registrasiënommer

BIO CIMETIDINE 200: 31/11.4.3/0679
BIO CIMETIDINE 400: 31/11.4.3/0680

Botswana:		
Bio Cimetidine 200 Reg. Nr. BOT0600855	S2	
Bio Cimetidine 400 Reg. Nr. BOT0600856	S2	

Zimbabwe:		
Bio Cimetidine 200 Reg. Nr. 96/16.7/3089	PP10	
Bio Cimetidine 400 Reg. Nr. 96/16.7/3090	PP10	

Namibië:		
Bio Cimetidine 200 Reg. Nr 12/11.4.3/0011	NS2	
Bio Cimetidine 400 Reg. Nr. 12/11.4.3/0012	NS2	