FORMATO PROSPETTI PREPIEGATI
DIMENSIONI: 190 x 240 mm x 2 = (190 x 480 mm)

A = Min. 6 mm

BAR INPUT

Max. 215 mm

Min. 170 mm

BIOTECH GABAPENTIN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS
S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
BIOTECH GABAPENTIN 100, gabapentin, 100 mg (capsules).
BIOTECH GABAPENTIN 300, gabapentin, 300 mg (capsules).
BIOTECH GABAPENTIN 400, gabapentin, 400 mg (capsules).

Read this entire leaflet carefully before you start taking BIOTECH GABAPENTIN.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- BIOTECH GABAPENTIN 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 DOES BIOTECH GABAPENTIN CONTAIN?
BIOTECH GABAPENTIN contains gabapentin as the active ingredient.
Other inactive ingredients are lactose monohydrate, maize starch, purified talc. The capsule consists of gelatine and colorants (titanium dioxide, red iron oxide and yellow iron oxide).
Contains sugar (lactose monohydrate)

2. WHAT BIOTECH GABAPENTIN IS USED FOR?
BIOTECH GABAPENTIN is used to treat epilepsy.

3. BEFORE YOU TAKE BIOTECH GABAPENTIN
Do not take BIOTECH GABAPENTIN if:
- you are allergic to any of the ingredients of BIOTECH GABAPENTIN
- you or your child is under the age of 12 years
- you are pregnant, trying for a baby, or breastfeeding.

Take special care with BIOTECH GABAPENTIN if:
You suffer from any kind of mental disorder, the use of BIOTECH GABAPENTIN can potentiate these effects. Please inform your doctor before you start taking BIOTECH GABAPENTIN.

You have a history of "Misuse, abuse potential or dependence"
Cases of misuse, abuse and dependence have been reported. If you have a history of misuse, abuse or dependence you should make your doctor of healthcare provided aware of this and you should be closely monitored.

You develop suicidal ideation and behaviour:
Suicidal ideation and behaviour have been reported in patients treated with Gabapentinoids in several indications. Therefore, patients should be monitored for signs of suicidal ideation and behaviours and appropriate treatment should be considered. Patients and caregivers should be advised to seek medical advice should sign of suicidal ideation or behaviour emerge.
You suffer from any type of kidney dysfunction.

If you are aware that you are intolerant towards Lactose (a milk sugar)
BIOTECH GABAPENTIN contains lactose and should not be used in patients with rare hereditary problems of lactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption.

If you are an epileptic patient:
Treatment should not be stopped abruptly and you may be having an epileptic seizure.
The discontinuation of BIOTECH GABAPENTIN treatment should be done gradually over a minimum of one week.
Do not stop taking these capsules before you have consulted with your doctor.

Taking BIOTECH GABAPENTIN with food and drink
Food does not alter the absorption of BIOTECH GABAPENTIN.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking BIOTECH GABAPENTIN.
Safety and efficacy during pregnancy and breastfeeding have not been established.

Driving and using machinery:
BIOTECH GABAPENTIN frequently causes dizziness and somnolence. Head and body injuries and road traffic incidents have also been reported with BIOTECH GABAPENTIN. Therefore, patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medication affects their ability to perform these activities.
The concomitant use of alcohol will intensify these effects.
Important information about some of the ingredients of BIOTECH GABAPENTIN
BIOTECH GABAPENTIN contains lactose 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 BIOTECH GABAPENTIN:
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
You should avoid the use of antacids that contain aluminium or magnesium concomitantly with BIOTECH GABAPENTIN. It is recommended that BIOTECH GABAPENTIN be taken at least two hours after the administration of an antacid.
BIOTECH GABAPENTIN is not expected to interact with other antiepileptic medicines or the oral contraceptive pill.
BIOTECH GABAPENTIN may interfere with some laboratory tests, if you require a urine test tell your doctor or hospital that you are taking BIOTECH GABAPENTIN.
Concurrent use of BIOTECH GABAPENTIN with alcohol and other CNS depressants may increase the CNS depressant effects e.g. decrease in alertness and increase in sleepiness.

4. HOW TO TAKE BIOTECH GABAPENTIN
Do not share medicines prescribed for you with any other person.
Always take BIOTECH GABAPENTIN exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of BIOTECH GABAPENTIN is too strong or too weak, talk to your doctor or pharmacist.
Your doctor will tell you how long your treatment will last as well as the dose of BIOTECH GABAPENTIN to start with and how to increase it.
If you are an elderly patient (over 65 years of age), you should take BIOTECH GABAPENTIN normally except if you have problems with your kidneys.
Your doctor may prescribe a different dosing schedule and/or dose if you have problems with your kidneys.
Always swallow the capsules whole with plenty of water.
Continue taking BIOTECH GABAPENTIN until your doctor tells you to stop.
If you have the impression that the effect of BIOTECH GABAPENTIN is too strong or too weak, tell your doctor or pharmacist.

If you take more BIOTECH GABAPENTIN than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Symptoms of overdose include dizziness, double vision, slurred speech, drowsiness, lethargy and mild diarrhoea.

If you forget to take BIOTECH GABAPENTIN:
If you forget to take a dose, take it as soon as you remember unless it is time for your next dose.
Do not take a double dose to make up for a forgotten individual dose.

5. POSSIBLE SIDE EFFECTS:
BIOTECH GABAPENTIN can have side effects. Not all side effects reported for BIOTECH GABAPENTIN are included in this leaflet. Should your general health worsen while taking BIOTECH GABAPENTIN, please consult your doctor, pharmacist or other health care professional for advice.

If the following side effects occur, medical attention is required. Please contact your doctor or nearest hospital as soon as possible:
Clumsiness or unsteadiness; continuous, uncontrolled back and forth and-or rolling eye movement.
Loss on memory; depression; suicidal ideation and behaviour, irritability or other mood or mental changes.

Medical attention is required for the following side effects only if they continue or become bothersome:
Dizziness; drowsiness; fatigue; muscle ache or pain; swelling of hands, feet or lower legs; trembling or shaking; vision abnormalities including blurred or double vision.
Weakness of loss of strength; dryness of mouth and throat; slurred speech; frequent urination; diarrhoea and indigestion; nausea and vomiting; headache; low blood pressure; trouble in sleeping; runny nose; dilatation of blood vessels; chest pain; rapid heartbeat.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF BIOTECH GABAPENTIN
Store in a cool (at or below 25 °C) dry place.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Do not use the capsules after the expiry date shown on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION
BIOTECH GABAPENTIN 100: Transparent PVC and printed aluminium foil blister strips containing 10 capsules packed in an outer carton containing 100 capsules.
BIOTECH GABAPENTIN 300: Transparent PVC and printed aluminium foil blister strips containing 10 capsules packed in an outer carton containing 100 capsules.
BIOTECH GABAPENTIN 400: Transparent PVC and printed aluminium foil blister strips containing 10 capsules packed in an outer carton containing 100 capsules.

8. IDENTIFICATION
BIOTECH GABAPENTIN 100: Size 3 hard gelatine capsule with white body and white cap, containing white crystalline powder.
BIOTECH GABAPENTIN 300: Size 1 hard gelatine capsule with yellow body and yellow cap, containing white crystalline powder.
BIOTECH GABAPENTIN 400: Size 0 hard gelatine capsule with orange body and orange cap, containing white crystalline powder.

9. REGISTRATION NUMBER/REFERENCE NUMBER
BIOTECH GABAPENTIN 100: 43/2.5/0332
BIOTECH GABAPENTIN 300: 43/2.5/0329
BIOTECH GABAPENTIN 400: 43/2.5/0333

10. NAME AND ADDRESS OF REGISTRATION HOLDER
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark,
Midrand, 6185
South Africa
Tel: 011 848 3050

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET
Date of registration: 27 November 2014.
Date of latest revision of the text as approved by Council: 27 November 2014.
Date of the PV update due to SAHPRA recommendation: 19 September 2019

PIL 430332/29/33-1

Linea di piega

Max. 215 mm

Min. 170 mm

BAR INPUT

A = Min. 6 mm

BIOTECH GABAPENTIN

PASIËNTINLIGTINGSBLAD

SKEDULERING STATUS
S3

HANDELSNAAM, FARMASEUTIESE VORM EN STERKTE
BIOTECH GABAPENTIN 100, gabapentin, 100 mg (kapsules).
BIOTECH GABAPENTIN 300, gabapentin, 300 mg (kapsules).
BIOTECH GABAPENTIN 400, gabapentin, 400 mg (kapsules).

Lees hierdie hele blad noukeurig deur voordat u begin om BIOTECH GABAPENTIN te drink.
- Hou hierdie blad. Dit mag nodig wees dat u dit weer moet lees.
- As u nog enige vrae het, moet u asseblief vir u dokter, apteker of ander gesondheidspraktisyn vra.
- BIOTECH GABAPENTIN 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.

1. WAT BIOTECH GABAPENTIN BEVAT?
BIOTECH GABAPENTIN bevat gabapentin as die aktiewe bestandeel.
Ander hulpstowwe is laktose monohidraat, mieliestysel, gesuiwerde talk. Die kapsule bevat gelatien en kleurmiddels (titanium dioksied, rooi ysteroksied en geel ysteroksied)
Bevat suiker (laktose monohidraat)

2. WAARVOOR BIOTECH GABAPENTIN GEBRUIK WORD
BIOTECH GABAPENTIN word gebruik om epilepsie te behandel.

3. WAT U MOET WEET VOORDAT U BIOTECH GABAPENTIN NEEM
Moenie BIOTECH GABAPENTIN neem as u:
- allergies is vir enige van die bestandeele van BIOTECH GABAPENTIN
- u of u kind onder die ouderdom van 12 jaar is
- u swanger is, as u beplan om swanger te raak of borsvoed

Wees besonder versigtig met BIOTECH GABAPENTIN indien:
U aan enige soort geestesversteuring ly, die gebruik van BIOTECH GABAPENTIN kan hierdie effekte verskerk. Lig asseblief u dokter in voordat u BIOTECH GABAPENTIN begin neem.

U 'n geskiedenis van "Misbruik, potensiële misbruik of afhanklikheid" het
Gevalle van misbruik, wangebruik en afhanklikheid is al aangemeld. As u 'n geskiedenis van misbruik, wangebruik en afhanklikheid het, moet u die dokter of gesondheidspraktisyn bewus maak daarvan en dit moet dan fyn dopgehou word.

As u selfmoordgedagtes –gedrag ontwikkel:
Selfmoordgedagtes en gedrag is al aangemeld in pasiënte wat met Gabatinoïede in verskeie indikasies behandel is. Daarom moet pasiënte dopgehou word vir tekens van selfmoordgedagtes en gedrag en toepaslike behandeling moet dan ooweeg word. Pasiënte en versorgers moet aangeraai word om mediese advies te win as selfmoordgedagtes of gedrag voorkom.
U aan enige tipe nierdisfunksie ly.

As u bewus is dat u 'n onverdraagsaamheid teenoor laktose het.('n melksuiker)
BIOTECH GABAPENTIN bevat laktose en moet nie gebruik word in pasiënte met skaars oorerflike probleme soos laktose onverdraagsaamheid, Lapp laktase ontoereikendheid of glukose-galaktose wanabsorpsie nie.

As u 'n epileptiese pasiënt is:
Behandeling moet nie skielik gestaak word nie, omdat u moontlik 'n epileptiese aanval kan kry.
Die staking van behandeling met BIOTECH GABAPENTIN moet geleidelik oor die minimum van 'n week gedoen word.
Moenie ophou om hierdie kapsules te neem voordat u met u dokter geraadpleeg het nie.

Neem van BIOTECH GABAPENTIN saam met kos en drank
Voedsel verander nie die absorpsie van BIOTECH GABAPENTIN nie.

Swangerskap en borsvoeding
As us swanger is of u baba borsvoed, raadpleeg asseblief u dokter, apteker of enige ander gesondheidspraktisyn vir advies, voordat u BIOTECH GABAPENTIN neem.
Veiligheid en effektiwiteit tydens swangerskap en borsvoeding is nie bepaal nie.

Motorbestuur en gebruik van masjinerie:
BIOTECH GABAPENTIN veroorsaak dikwels duiselighed en slaperighed. Daarom word pasiënte aangeraai om nie te bestuur, ingewikkelde masjinerie te bestuur of ander moontlike gevaarlike aktiwiteite te beoefen nie, totdat dit bekend is of hierdie medikasie hul vermoë om hierdie aktiwiteite uit te voer, beïnvloed. Die gesamentlike gebruik van alkohol sal hierdie effekte verster.

Belangrike inligting oor sommige van die bestanddele van BIOTECH GABAPENTIN
BIOTECH GABAPENTIN bevat laktose en moet nie toegedien word aan pasiënte met skaars oorerflike probleme soos laktose onverdraagsaamheid, Lapp laktase ontoereikendheid of glukose-galaktose wanabsorpsie nie.

Ander medisyne en BIOTECH GABAPENTIN:
Sê altyd vir u gesondheidsorgverskaffer as u enige ander medisyne gebruik (waaronder alle aanvullende of tradisionele medisyne).
U moet die gebruik van teensuurmiddels wat aluminium of magnesium bevat saam met BIOTECH GABAPENTIN vermy. Dit word aanbeveel dat u BIOTECH GABAPENTIN neem, ten minste twee ure nadat u die teensuurmiddel geneem het.
Daar word nie verwag dat BIOTECH GABAPENTIN interaksie sal hê met ander antiepileptiese middels of met die orale voorbehoedpil nie.
BIOTECH GABAPENTIN kan met 'n paar laboratoriumtoetse inmeng, as u 'n urinetoets benodig, moet u u dokter of hospitaal inlig dat u BIOTECH GABAPENTIN neem.
Gelyktydige gebruik van BIOTECH GABAPENTIN met alkohol en ander SSS -depressante kan die SSS -depressiewe effek verhoog, bv. afname in waaksaamheid en toename in slaperigheid.

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4. HOE OM BIOTECH GABAPENTIN TE NEEM

Moenie medisyne wat vir u voorgeskryf is vir enige ander persoon gee nie.
Gebruik BIOTECH GABAPENTIN altyd presies soos wat u dokter of apteker vir u gesê het.
Raadpleeg u dokter of apteker as u nie seker is nie. Sê vir u dokter of apteker as u die indruk het dat die effek van BIOTECH GABAPENTIN te sterk of te swak is.
U dokter sal u inlig oor hoe lank die behandeling met BIOTECH GABAPENTIN sal duur en ook met watter dosis u moet begin, en ook hoe om die dosis te verhoog.
As 'n bejaarde pasiënt is (ouer as 65 jaar), moet u BIOTECH GABAPENTIN normaalweg neem, behalwe as u probleme met u niere het.
U dokter kan 'n ander doseringsskedule en/of dosis voorskryf as u nierprobleme het.
Sluk altyd die kapsules heel met baie water.
Sê vir u dokter of apteker as u die indruk het dat die effek van BIOTECH GABAPENTIN te sterk of te swak is.

As u meer BIOTECH GABAPENTIN gedrink het as wat u moes:
Raadpleeg u dokter of apteker onmiddellik in geval van oordosering. As nie een beskikbaar is nie, kontak die naaste hospitaal of giftsentrum. Simptome van 'n oordosis sluit in duiselighed, dubbele sig, onduidelike spraak, slaperigheid, lustelooshed en ligte diarree.

As u vergeet om BIOTECH GABAPENTIN te neem:
As u vergeet om 'n dosis te neem, neem dit so gou as wat u onthou, tensy dit tyd is vir u volgende dosis. Moenie 'n dubbele dosis neem om 'n vergete individuele dosis te vergoed nie.

5. MOONTLIKE NEWE-EFFEKTE:
BIOTECH GABAPENTIN kan newe-effekte hê. Nie al die newe-effekte wat vir BIOTECH GABAPENTIN aangemeld is, is in hierdie blad opgeneem nie. As u algemene gesondheidstoestand vererger of as u newe-effekte ervaar terwyl u BIOTECH GABAPENTIN gebruik, moet u u dokter, apteker of enige ander gesondheidskundige om advies raadpleeg.

As enige van die volgende newe-effekte voorkom, word mediese aandag benodig. Kontak asseblief u dokter of naaste hospitaal so gou moontlik:
Lomphéid of onstabiliteit; aanhoudende, onbeheerde heen en weer en-of rollende oogbeweging.
Verlies aan geheue; depressie; selfmoordgedagtes en -gedrag, prikkelbaarheid of ander bui of geestelike veranderinge.

Mediese aandag is nodig vir die volgende newe-effekte, sleg as dit aanhou of lastig raak:
Duiseligheid; lomerigheid; moegheid; spierpyn of pyn; swelling van hande, voete of onderbene; bewe of skud; geslagfunksies, insluitend vaag of dubbelvisie.
Swakheid en verlies aan krag; droë mond en keel; slapende spraak; gereelde urineering; diarree en swak spysvertering; naarheid en opgooi; hoofpyn; lae bloeddruk; probleme met slaap; loopneus; dilatasie van bloedvate; borspyn; vinnige hartklop.
As u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, moet u u dokter of apteker daarvan in kennis stel.

6. BERGING EN VERNIETIGING VAN BIOTECH GABAPENTIN

Bêre in 'n koel (op of onder 25 °C) droë plek.
BÊRE ALLE MEDISYNE BUITE BEREIK VAN KINDERS.
Ooshandig alle ongebruikte medisyne aan u apteker.
Moenie ongebruikte medisyne in drein of rioolstelsels (bv. Toilette) weggooi nie.

7. AANBIEDING

BIOTECH GABAPENTIN 100: Deursigtige blisterstrokе van PVC en gedrukte aluminiumfoelie met 10 kapsules verpak in 'n buitenste kartoondoos met 100 kapsules.
BIOTECH GABAPENTIN 300: Deursigtige blisterstrokе van PVC en gedrukte aluminiumfoelie met 10 kapsules verpak in 'n buitenste kartoondoos met 100 kapsules.
BIOTECH GABAPENTIN 400: Deursigtige blisterstrokе van PVC en gedrukte aluminiumfoelie met 10 kapsules verpak in 'n buitenste kartoondoos met 100 kapsules.

8. IDENTIFIKASIE

BIOTECH GABAPENTIN 100: Grootte 3 harde gelatienkapsule met 'n wit lyf en 'n wit dop, wat wit kristallyne poeier bevat.
BIOTECH GABAPENTIN 300: Grootte 1 harde gelatienkapsule met geel lyfe en geel dop, wat wit kristallyne poeier bevat.
BIOTECH GABAPENTIN 400: Grootte 0 harde gelatienkapsule met oranje lyf en oranje dop, wat wit kristallyne poeier bevat.

9. REGISTRASIENOMMER/VERWYSINGSNOMMER

BIOTECH GABAPENTIN 100: 43/2.5/0332
BIOTECH GABAPENTIN 300: 43/2.5/0329
BIOTECH GABAPENTIN 400: 43/2.5/0333

10. NAAM EN ADRES VAN DIE REGISTRASIE HOUER

Biotech Laboratories (Edms) Bpk
Grond Vloer, Blok K Wes, Central Park
400 16de Weg, Randjespark,
Midrand, 6185
Suid Afrika
Tel: 011 848 3050

11. DATUM VAN PUBLIKASIE VAN DIE PASIËNTINLIGTINGSBLAD

Datum van registrasie: 27 November 2014.
Datum van die laaste hersiening van die teks soos goedgekeur deur die Raad:
27 November 2014.
Datum van die PV opdatering soos deur SAHPRA aanbeveel: 19 September 2019