BIOTECH GABAPENTIN

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:
S3

BIOTECH GABAPENTIN 100, gabapentin, 100 mg (capsules).
BIOTECH GABAPENTIN 300, gabapentin, 300 mg (capsules).
BIOTECH GABAPENTIN 400, gabapentin, 400 mg (capsules).
Gabapentin
Contains sugar (lactose monohydrate)
BIOTECH GABAPENTIN 100 contains 16,833 mg;
BIOTECH GABAPENTIN 300 contains 50,50 mg and
BIOTECH GABAPENTIN 400 contains 67,33 mg per capsule

Read all of this 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, pharmacist, nurse or other healthcare provider.
- 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.

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

1. What BIOTECH GABAPENTIN is and what it is used for
BIOTECH GABAPENTIN is used to treat epilepsy.

2. What you need to know before you take BIOTECH GABAPENTIN
Do not take BIOTECH GABAPENTIN if:
- You are hypersensitive (allergic) to gabapentin or any of the ingredients of BIOTECH GABAPENTIN (listed in section 6);
- you or your child is under the age of 12 years;
- you are pregnant, trying for a baby, or breastfeeding.

Warnings and precautions
Some people taking BIOTECH GABAPENTIN get an allergic reaction or potentially serious skin reaction, which may develop into more serious problems if they are not treated. Serious skin rashes including Stevens-Johnson syndrome, toxic epidermal necrolysis and drug reaction with eosinophilia and systemic symptoms (DRESS) have been reported in association with gabapentin (see section 4).

If you experience any of the following symptoms, stop taking this medicine 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;
- fever, rash and/or itching;
- feeling faint or dizzy.

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

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.
- If you develop signs such as persistent stomach pain, feeling sick and being sick contact your doctor immediately as these may be symptoms of acute pancreatitis (an inflamed pancreas).
- If you have nervous system disorders, breathing disorders, or you are more than 65 years old, your doctor may prescribe you a different dosing schedule.
- If you have a history of "Misuse, abuse potential or dependence"
  - Before taking this medicine, tell your doctor if you have ever abused or been dependent on alcohol, prescription medicines or illegal medicines; it may mean you have a greater risk of becoming dependent on BIOTECH GABAPENTIN.
  - Cases of misuse, abuse and dependence have been reported. If you have a history of misuse, abuse or dependence you should make your doctor or healthcare provider aware of this and you should be closely monitored.
- Some people may become dependent on BIOTECH GABAPENTIN (a need to keep taking the medicine). They may have withdrawal effects when they stop using BIOTECH GABAPENTIN (see section 3). If you have concerns that you may become dependent BIOTECH GABAPENTIN , it is important that you consult your doctor.
  - 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.
- If 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 (thoughts of harming or killing themselves) and appropriate treatment should be considered. Patients and caregivers should be advised to seek medical advice should sign of suicidal ideation or behaviour emerge.
- If you are an epileptic patient:
  - Treatment should not be stopped abruptly, and you may be having an epileptic seizure.
  - Increase in seizures or new types of seizure may occur in some people being treated with BIOTECH GABAPENTIN. Talk to your doctor or pharmacist if you notice a change to your condition.
- If you experience any of the following symptoms: feeling dizzy and drowsy (which could increase accidental injury), confusion, loss of consciousness and reduced mental state while taking BIOTECH GABAPENTIN, talk to you doctor or pharmacist for advice.
- If you suffer from kidney problems your doctor may prescribe a different dosing schedule.
- If you are on haemodialysis (to remove waste products because of kidney failure), tell your doctor.

Children
Safety and efficacy in children under 12 years of age has not been established (see section "Do not take").

Other medicines and BIOTECH GABAPENTIN
Always tell your healthcare provider if you are taking any other medicine. (This includes all 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, including opioids (such as morphine), may increase the CNS depressant effects e.g., decrease in alertness (drowsiness), increase in sleepiness, difficulty breathing, sedation, or death.

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

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 healthcare provider for advice before taking BIOTECH GABAPENTIN.

Safety and efficacy during pregnancy have not been established.
BIOTECH GABAPENTIN capsules should not be taken during pregnancy.
Effective contraception must be used by women of child-bearing potential.
There have been no studies specifically looking at the use of BIOTECH GABAPENTIN in pregnant women, but it may increase the risk of harm to the foetus, particularly when taken at the same time as other medicines to treat seizures.

Do not suddenly stop taking this medicine as this may lead to breakthrough seizures, which could have serious consequences for you and your baby.

You should not take BIOTECH GABAPENTIN while you are breastfeeding.
BIOTECH GABAPENTIN is passed through human milk. Because the effect on the baby is unknown, it is not recommended to breast-feed while taking BIOTECH GABAPENTIN.

Fertility
No data on male and female fertility is available.

Driving and using machines
Special care should be taken by patients driving, operating machinery or performing any hazardous tasks.
BIOTECH GABAPENTIN may cause dizziness, drowsiness and somnolence (tiredness).
Even, if they were only of mild or moderate degree, these undesirable effects could be potentially dangerous in patients driving or operating machinery, especially at the start of treatment or after a dose increase.
Head and body injuries and road traffic incidents have also been reported with BIOTECH GABAPENTIN.
The concomitant use of alcohol will intensify these effects.

It is not always possible to predict to what extent BIOTECH GABAPENTIN may interfere with your daily activities. You should ensure that you do not engage in driving and use machines until you are aware of the measure to which BIOTECH GABAPENTIN affects you.

BIOTECH GABAPENTIN contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BIOTECH GABAPENTIN.

3. 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 told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with BIOTECH GABAPENTIN 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 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.

If you stop taking BIOTECH GABAPENTIN
Do not suddenly stop taking BIOTECH GABAPENTIN. If you want to stop taking BIOTECH GABAPENTIN, discuss this with your doctor first. They will tell you how to do this. If your treatment is stopped it should be done gradually over a minimum of 1 week.
After stopping a short or long-term treatment with BIOTECH GABAPENTIN, you need to know that you may experience certain side effects, so-called withdrawal effects. These effects can include seizures, anxiety, difficulty sleeping, feeling sick (nausea), pain, sweating, shaking, headache, depression, feeling abnormal, dizziness, and feeling generally unwell.
These effects usually occur within 48 hours after stopping BIOTECH GABAPENTIN. experience withdrawal effects, you should contact your doctor.

4. 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 or if you experience any untoward effects while taking BIOTECH GABAPENTIN, please consult your healthcare provider for advice.

If any of the following happens, stop taking BIOTECH GABAPENTIN and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes. These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis);
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome);
- severe skin reactions that require immediate attention, swelling of the lips and face, skin rash and redness, and/or hair loss (these may be symptoms of a serious allergic reaction);
- BIOTECH GABAPENTIN capsules may cause a serious or life-threatening allergic reaction that may affect your skin or other parts of your body such as your liver or blood cells. You may or may not have a rash when you get this type of reaction. It may cause you to be hospitalised or to stop BIOTECH GABAPENTIN capsules;
- persistent stomach pain, feeling sick and being sick as these may be symptoms of acute pancreatitis (an inflamed pancreas);
- patients and caregivers should seek medical attention immediately if the patient experiences symptoms of respiratory problems because these can be life-threatening.

Symptoms to watch for include:
- Confusion or disorientation
- Unusual dizziness or light-headedness
- Extreme sleepiness or lethargy
- Slowed, shallow, or difficult breathing
- Unresponsiveness, which means a person does not answer or react normally or you cannot wake them up
- Bluish-coloured or tinted skin, especially on the lips, fingers, and toes.

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

Tell your doctor if you notice any of the following:
Frequent side effects:
- Viral infection;
- pneumonia, respiratory infection, urinary tract infection, inflammation of the ear or other infections;
- low white blood cell counts;
- anorexia, increased appetite;
- anger towards others, confusion, mood or mental changes, depression, anxiety, nervousness, difficulty with thinking;
- clumsiness or unsteadiness (ataxia), drowsiness, dizziness, lack of coordination;
- convulsions, jerky movements, slurred speech, loss of memory, trembling or shaking (tremor), trouble in sleeping, headache, sensation such as pins and needles, decreased sensation (numbness), difficulty with coordination, continuous, uncontrolled back and forth and/or rolling eye movement (nystagmus), increased, decreased or absent reflexes;
- vision abnormalities including blurred or double vision;
- vertigo;
- low blood pressure, high blood pressure, dilatation of blood vessels;
- difficulty breathing, bronchitis, sore throat, cough, runny nose;
- vomiting (being sick), nausea (feeling sick), problems with teeth, inflamed gums, diarrhoea, stomach pain, indigestion, constipation, dryness of mouth and throat, flatulence;
- facial swelling, bruises, rash, itchy skin, acne;
- joint pain, muscle ache or pain, back pain, twitching;
- difficulties with erection (impotence);
- fatigue (feeling tired), fever, swelling of hands, feet or lower legs, difficulty with walking, weakness of loss of strength, pain, feeling unwell, flu-like symptoms;
- decrease in white blood cells, increase in weight or
- accidental injury, fracture, abrasion.

Less frequent side effects:
- Allergic reactions such as hives;
- increase and decrease in blood glucose levels (most often observed in patients with diabetes);
- agitation (a state of chronic restlessness and unintentional and purposeless motions);
- decreased movement, mental impairment; loss of consciousness;
- rapid heartbeat;
- trouble breathing, shallow breaths (respiratory depression);
- difficulty swallowing;
- frequent urination;
- swelling that may involve the face, trunk and limbs;
- abnormal blood test results suggesting problems with the liver or
- fall.

After marketing BIOTECH GABAPENTIN, the following side effects have been reported
Frequency unknown:
- Decreased platelets (blood clotting cells);
- low blood sodium level;
- chest pain;
- ringing in the ears;
- inflammation of the liver, yellowing of the skin and eyes (jaundice);
- adverse events following the abrupt discontinuation of BIOTECH GABAPENTIN (anxiety, difficulty sleeping, feeling sick, pain, sweating);
- change in blood test results (creatine phosphokinase increased);
- breakdown of muscle fibers (rhabdomyolysis);
- problems with abnormal/ involuntary movements such as writhing, jerking, movements and stiffness;
- suicidal ideation and behaviour;
- hallucinations;
- becoming dependent on BIOTECH GABAPENTIN ('medicine dependence');
- acute kidney failure, incontinence;
- increased breast tissue, breast enlargement;
- problems with sexual functioning including inability to achieve a sexual climax, delayed ejaculation.

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 BIOTECH GABAPENTIN.

5. How to store BIOTECH GABAPENTIN
Store at or below 25 °C in a 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).

6. Contents of the pack and other information
What BIOTECH GABAPENTIN contains:
The active substance is gabapentin.
The other ingredients are lactose monohydrate, maize starch, purified talc. The capsule consists of gelatine and colorants (titanium dioxide, red iron oxide and yellow iron oxide).

What BIOTECH GABAPENTIN looks like and contents of the pack
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.

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.

Holder of Certificate of Registration
Biotech Laboratories (Pty) Ltd
Ground Floor, Block K West, Central Park
400 16th Road, Randjespark,
Midrand, 1685
South Africa
Tel: 011 848 3050

This leaflet was last revised in
8 March 2023

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

BIOTECH GABAPENTIN

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS:
S3

BIOTECH GABAPENTIN 100, gabapentien, 100 mg (kapsules).
BIOTECH GABAPENTIN 300, gabapentien, 300 mg (kapsules).
BIOTECH GABAPENTIN 400, gabapentien, 400 mg (kapsules).
Gabapentien
Bevat suiker (laktosemonohidraat)
BIOTECH GABAPENTIN 100 bevat 16,833 mg;
BIOTECH GABAPENTIN 300 bevat 50,50 mg en
BIOTECH GABAPENTIN 400 bevat 67,33 mg in elke kapsule

Lees die hele pamflet noukeurig deur voordat jy BIOTECH GABAPENTIN begin neem.
- Bewaar hierdie pamflet. Jy mag dit dalk weer moet lees.
- As jy verdere vrae het, vra asseblief vir jou dokter, apteker, verpleegster of ander gesondheidsorgverskaffer.
- BIOTECH GABAPENTIN is persoonlik vir jou voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie pamflet

1. Wat BIOTECH GABAPENTIN is en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy BIOTECH GABAPENTIN neem
3. Hoe om BIOTECH GABAPENTIN te neem
4. Moontlike newe-effekte
5. Hoe om BIOTECH GABAPENTIN te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat BIOTECH GABAPENTIN is en waarvoor dit gebruik word

BIOTECH GABAPENTIN word gebruik om epilepsie te behandel.

2. Wat jy moet weet voordat jy BIOTECH GABAPENTIN neem

Moenie BIOTECH GABAPENTIN neem nie as:
- Jy allergies (hipersensitief) vir gabapentien of enige van die ander bestanddele in BIOTECH GABAPENTIN is (gelys in afdeling 6)
- Jy of jou kind jonger as 12 jaar oud is
- Jy swanger is, probeer swanger raak of jou baba borsvoed nie.

Waarskuwings en voorsorgmaatreëls

Sommige mense wat BIOTECH GABAPENTIN neem, kry 'n allergiese reaksie of potensieel ernstige velreaksie, wat in meer ernstige probleme kan ontwikkel as hulle nie behandel word nie. Ernstige veluitslag insluitend Stevens Johnson se sindroom, toksiese epidermale nekrolise en geneesmiddelreaksie met eosinofilie en sistemiese simptome (DRESS) is in verband met gabapentien aangemeld (sien afdeling 4).

Indien jy enige van die volgende simptome opmerk, hou op om hierdie medisyne te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel wat moeilike asemhaling of moeilike sluk mag veroorsaak;
- Koors, uitslag en/ of jeuk;
- 'n flou of duiselige gevoel

Hierdie is alles baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige reaksie op BIOTECH GABAPENTIN gehad. Jy benodig dalk dringende mediese aandag of hospitalisasie.

Neem spesiale sorg met BIOTECH GABAPENTIN:
- Indien jy aan enige tipe geestesversteuring ly aangesien die gebruik van BIOTECH GABAPENTIN hierdie effekte kan potensieer. Vertel asseblief jou dokter voordat jy begin om BIOTECH GABAPENTIN te neem.
- Indien jy tekens soos aanhoudende maagpyn, siek voel en siek wees ontwikkel, kontak jou dokter dadelik aangesien dit simptome van akute pankreatitis ('n ontsteekte pankreas) kan wees.
- Indien jy senuweestelselafwykings, asemhalingsversteurings het, of as jy ouer as 65 jaar oud is, kan jou dokter vir jou 'n ander doseringskedule voorskryf.
- Indien jy 'n geskiedenis van "Misbruik of afhanklikheidspotensiaal het"
  – Voordat jy hierdie medisyne neem, vertel jou dokter as jy al ooit alkohol, voorskrifmedisyne of onwettige medisyne misbruik of daarvan afhanklik was; dit kan beteken dat jy 'n groter risiko het om van BIOTECH GABAPENTIN afhanklik te word.
  – Gevalle van misbruik en afhanklikheid is gerapporteer. Indien jy 'n geskiedenis van misbruik of afhanklikheid het moet jy jou dokter of gesondheidsorgverskaffer bewus maak van dit en jy moet noukeurig gemonitor word.
- Sommige mense kan afhanklik word van BIOTECH GABAPENTIN ('n behoefte om aan te hou om die medisyne te neem). Hulle kan onttrekkingseffekte hê wanneer hulle ophou om BIOTECH GABAPENTIN te gebruik (sien afdeling 3). As jy bekommerd is dat jy afhanklik kan word BIOTECH GABAPENTIN, is dit belangrik dat jy jou dokter raadpleeg.
  - Die staking van BIOTECH GABAPENTIN behandeling moet geleidelik gedoen word oor 'n miminum van een week.
  - Moenie ophou om hierdie kapsules te neem voordat jy jou dokter geraadpleeg het nie.
- Indien jy selfmoordgedagtes en gedrag ontwikkel:
  – Selfmoordgedagtes en gedrag is gerapporteer in pasiënte wat met Gabapentinoïede behandel is vir verskeie indikasies. Daarom moet pasiënte gemonitor word vir tekens van selfmoordgedagtes en gedrag (gedagtes om jouself seer te maak of dood te maak) en toepaslike behandeling moet oorweeg word. Pasiënte en versorgers moet aangeraai word om mediese advies in te win indien daar tekens van selfmoordgedagtes en gedrag te vore kom.
- Indien jy 'n epileptiese pasiënt is:
  – Behandeling moet nie skielik gestaak word nie en jy mag 'n epileptiese aanval hê.
  – 'n Toename in aanvalle of nuwe tipes aanvalle kan voorkom by sommige mense wat met BIOTECH GABAPENTIN behandel word. Praat met jou dokter of apteker as jy 'n verandering in jou toestand opmerk.
- Indien jy die volgende simptome ervaar: duiselig en lomerig voel (wat toevallige besering kan verhoog), verwarring, verlies van bewussyn en verminderde geestestoestand terwyl jy BIOTECH GABAPENTIN neem, praat met jou dokter of apteker vir raad.
- Indien jy aan nierprobleme ly, mag jou dokter dalk 'n ander dosisskedule voorskryf.
- Indien jy op hemodialise is (om afvalprodukte te verwyder as gevolg van nierversaking), vertel jou dokter.

Kinders

Veiligheid en doeltreffendheid in kinders jonger as 12 jarige ouderdom is nog nie vasgestel nie (sien afdeling 'Moenie neem nie").

Ander medisyne en BIOTECH GABAPENTIN

Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.)
- Jy moet die gesamentlike gebruik van teensuurmiddels wat aluminium of magnesium bevat en BIOTECH GABAPENTIN vermy. Dit word aanbeveel dat BIOTECH GABAPENTIN ten minste twee ure na die toediening van 'n teensuurmiddel geneem moet word.
- BIOTECH GABAPENTIN word nie verwag om 'n interaksie met enige ander anti-epileptiese medisyne of die orale voorbehoedpil te hê nie.
- BIOTECH GABAPENTIN mag inmeng met sekere laboratoriumtoetse. Indien jy 'n urientoets moet doen vertel jou dokter of hospitaal dat jy BIOTECH GABAPENTIN neem.
- Gelyktydige gebruik van BIOTECH GABAPENTIN met alkohol en ander SSS depressante, insluitend opioïede (soos morfien), mag die SSS onderdrukkende effekte verhoog bv. verlaagde waaksaamheid (slaperigheid), verhoogde slaperigheid, moeilike asemhaling, sedasie of dood.

BIOTECH GABAPENTIN met kos en drank

Kos verander nie die absorpsie van BIOTECH GABAPENTIN nie.

Swangerskap en borsvoeding

Indien jy swanger is of jou baba borsvoed, dink dat jy swanger mag wees of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy BIOTECH GABAPENTIN neem.

Veiligheid en doeltreffendheid gedurende swangerskap is nog nie vasgestel nie.
BIOTECH GABAPENTIN kapsules moet nie tydens swangerskap geneem word nie.
Doeltreffende voorbehoedmiddels moet deur vroue van vrugbare potensiaal gebruik word.
Daar was geen studies wat spesifiek na die gebruik van BIOTECH GABAPENTIN by swanger vroue kyk nie, maar dit kan die risiko van skade aan die fetus verhoog, veral wanneer dit gelyktydig met ander medisyne geneem word om aanvalle te behandel.

Moenie skielik ophou om hierdie medisyne te gebruik nie, want dit kan lei tot deurbraak aanvalle, wat ernstige gevolge vir jou en jou baba kan hê.

Jy moet nie BIOTECH GABAPENTIN neem terwyl jy borsvoed nie.
BIOTECH GABAPENTIN word in menslike melk uitgeskei. Omdat die effek op die baba onbekend is, word dit nie aanbeveel om te borsvoed terwyl BIOTECH GABAPENTIN geneem word nie.

Vrugbaarheid

Geen data oor manlike en vroulike vrugbaarheid is beskikbaar nie.

Bestuur en die gebruik van masjiene

Spesiale sorg moet geneem word deur pasiënte wat bestuur, masjinerie gebruik of enige gevaarlike take verrig.
BIOTECH GABAPENTIN veroorsaak mag duiseligheid, lomerigheid en moegheid veroorsaak.
Selfs as hulle slegs van ligte of matige graad was, kan hierdie ongewenste effekte potensieel gevaarlik wees in pasiënte wat bestuur of masjinerie gebruik, veral aan die begin van behandeling of na 'n dosisverhoging.
Kop en liggaamsbeserings en verkeersongelukke is ook gerapporteer met BIOTECH GABAPENTIN.
Die gelyktydige gebruik van alkohol sal hierdie effekte verskerp.

Dit is nie altyd moontlik om te voorspel tot watter mate BIOTECH GABAPENTIN mag inmeng met jou daaglikse aktiwiteite nie. Jy moet seker maak dat jy nie 'n motor bestuur of masjinerie gebruik totdat jy bewus is van die mate waartoe BIOTECH GABAPENTIN jou affekteer nie.

BIOTECH GABAPENTIN bevat laktose

Indien jy deur jou dokter vertel is dat jy 'n onverdraagsaamheid het vir sekere suikers, raadpleeg asseblief jou dokter voordat jy BIOTECH GABAPENTIN neem.

3. Hoe om BIOTECH GABAPENTIN te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander person deel nie.
Neem altyd BIOTECH GABAPENTIN presies soos jou dokter jou vertel het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.

Jou dokter sal jou vertel hoe lank jou behandeling met BIOTECH GABAPENTIN gaan aanhou, asook die dosis van BIOTECH GABAPENTIN waarmee jy moet begin en hoe om dit te verhoog.

Indien jy 'n bejaarde pasiënt is (ouer as 65 jaar) moet jy BIOTECH GABAPENTIN soos normaal neem, behalwe as jy probleme met jou niere het.
Jou dokter mag 'n veranderde dosisskedule en/ of dosis voorskryf indien jy probleme met jou niere het.
- Sluk altyd die kapsules heel met genoeg water.
- Hou aan om BIOTECH GABAPENTIN te neem totdat jou dokter vir jou vertel om op te hou.

Indien jy onder die indruk is dat die effek van BIOTECH GABAPENTIN te sterk of te swak is, vertel jou dokter of apteker.

Indien jy meer BIOTECH GABAPENTIN neem as wat jy moet

In die geval van 'n oordosis, raadpleeg jou dokter of apteker. Indien hulle nie beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.
Simptome van oordosering sluit duiseligheid, dubbelvisie, sleepspraak, lomerigheid, lusteloosheid en matige diarree in.

Indien jy vergeet om BIOTECH GABAPENTIN te neem

Indien jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, tensy dit reeds tyd is vir jou volgende dosis. Moenie 'n dubbeldosis neem om op te maak vir 'n vergete individuele dosis nie.

Indien jy ophou om BIOTECH GABAPENTIN te neem

Moenie skielik ophou om BIOTECH GABAPENTIN te neem nie. As jy wil ophou om BIOTECH GABAPENTIN te neem, bespreek dit eers met jou dokter. Hulle sal jou vertel hoe om dit te doen. As jou behandeling gestaak word, moet dit geleidelik oor 'n minimum van 1 week gedoen word.
Nadat jy 'n kort- of langtermynbehandeling met BIOTECH GABAPENTIN gestaak het, moet jy weet dat jy sekere newe-effekte kan ervaar, sogenaamde onttrekkingseffekte. Hierdie effekte kan aanvalle, angs, moeilike slaap, siek voel (naarheid), pyn, sweet, skudding, hoofpyn, depressie, abnormale gevoel, duiseligheid en algemene onwel gevoel insluit.
Hierdie effekte kom gewoonlik voor binne 48 uur nadat BIOTECH GABAPENTIN gestaak is. Indien jy onttrekkingseffekte ervaar, moet jy jou dokter kontak.

4. Moontlike newe-effekte

BIOTECH GABAPENTIN kan newe-effekte hê.
Nie alle newe-effekte wat vir BIOTECH GABAPENTIN gerapporteer is word in hierdie inligtingspamflet ingesluit nie. As jou algemene gesondheid sou versleg of as jy enige ongewenste effekte ervaar terwyl jy BIOTECH GABAPENTIN neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om BIOTECH GABAPENTIN te neem en vertel jou dokter onmiddelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- Rooierige nie-verhewe, teikenagtige of sirkelvormige kolle op die romp, dikwels met sentrale blase, velafskilfering, sere van die mond, keel, neus, geslagsdele en oë. Hierdie ernstige veluitslag kan voorafgegaan word deur koors en griepagtige simptome (Stevens-Johnson-sindroom, toksiese epidermale nekrolise);
- wydverspreide uitslag, hoë liggaamstemperatuur en vergrote limfknope (DRESS-sindroom of geneesmiddel-hipersensitiwiteitsindroom);
- ernstige velreaksies wat onmiddellike aandag vereis, swelling van die lippe en gesig, veluitslag en rooiheid, en/ of haarverlies (dit kan simptome van 'n ernstige allergiese reaksie wees);
- BIOTECH GABAPENTIN kapsules mag 'n ernstige of lewensbedreigende allergiese reaksie veroorsaak wat jou vel of ander dele van jou liggaam soos jou lewer of bloedselle kan beïnvloed. Jy mag of mag nie 'n uitslag hê wanneer jy hierdie tipe reaksie kry nie. Dit kan veroorsaak dat jy in die hospitaal opgeneem word of BIOTECH GABAPENTIN-kapsules stop;
- aanhoudende maagpyn, siek gevoel, siek wees, aangesien hierdie simptome van akute pankreatitis kan wees ('n ontsteekte pankreas)
- pasiënte en versorgers moet onmiddelik mediese aandag inwin indien die pasiënt simptome van asemhalingsprobleme ervaar, aangesien hierdie lewensbedreigend kan wees.

Simptome sluit in:
– Verwarring of disoriëntasie
– Ongewone duiseligheid of lighoofdigheid
– Uiterste slaperigheid of lusteloosheid
– Stadige, vlak of moeilike asemhaling
– 'n Persoon wat nie reageer nie, wat beteken dat 'n person nie normaal antwoord of reageer nie of jy kan hom/ haar nie wakker maak nie.
– Blouerige of getinte vel, veral op die lippe, vingers en tone.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit het, het jy dalk 'n ernstige reaksie vir BIOTECH GABAPENTIN gehad. Jy mag dringende mediese aandag of hospitalisasie nodig hê.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde newe-effekte:
- Virale infeksie;
- Longontsteking, respiratoriese infeksie, urienweginfeksie, oorontsteking of ander infeksies;
- Lae witbloedseltellings;
- Anoreksie, verhoogde aptyt;
- Kwaad gevoel teenoor ander, verwarring, gemoed- of geestelike veranderings, depressie, angstigheid, senuweeagtigheid, moeilike denke;
- Lompheid of onbestendigheid (ataksie), lomerigheid, duiseligheid, gebrek aan koördinasie;
- Stuiptrekkings/ aanvalle, rukkerige bewegings, onduidelike spraak, geheueverlies, bewing, probleme met slaap, hoofpyn, sensasie soos spelde en naalde, verminderde sensasie (gevoelloosheid), probleme met koördinasie, aanhoudende, onbeheerde heen en weer en/of rol oogbeweging (nystagmus), verhoogde, verminderde of afwesige reflekse;
- Sigversteurings, insluitend dowwe of dubbelvisie;
- Vertigo;
- Lae bloeddruk, hoë bloeddruk, dilatasie van bloedvate;
- Moeilike asemhaling, bronchitis, seer keel, hoes, loopneus;
- Braking (siek wees), naarheid (siek gevoel), probleme met tande, ontsteekte tandvleis, diarree, maagpyn, slegte spysvertering, hardlywigheid, droogheid van mond en keel, winderigheid;
- Swelling van die gesig, kneusing, uitslag, jeukerige vel, aknee;
- Gewrigspyn, spierpyn, rugpyn, ruk;
- Moeilikheid met ereksie (impotensie);
- Moegheid (moeg gevoel), koors, swelling van hande, voete of onderbene, moeilikheid om te loop, swakheid of kragverlies, pyn, onwel voel, griepagtige simptome;
- Verlaging in witbloedselle, toename in liggaamsgewig of
- Toevallige besering, fraktuur, skuur.

Minder gereelde newe-effekte:
- Allergiese reaksies soos korwe;
- Verhoging en verlaging in bloedglukosevlakke (meestal waargeneem by pasiënte met diabetes);
- Agitasie ('n toestand van chroniese rusteloosheid en onbedoelde en doellose bewegings);
- Verminderde beweging, verstandelike gestremdheid; verlies van bewussyn;
- Vinnige hartklop;
- Moeilike asemhaling, vlak asemhalings (respiratoriese onderdrukking);
- Moeilike sluk;
- Gereelde urinering;
- Swelling wat die gesig, lyf en ledemate mag affekteer;
- Abnormale bloedtoetsresultate wat dui op probleme met die lewer of
- Val.

Na die bemarking van BIOTECH GABAPENTIN is die volgende newe-effekte aangemeld:

Frekwensie onbekend:
- Verlaagde bloedplaatjies (bloedstollingsselle);
- Lae bloednatriumvlak;
- Borspyn;
- Gelui in die ore;
- Inflammasie van die lewer, vergeling van die vel en oë (geelsug);
- Newe-effekte na die skielike staking van BIOTECH GABAPENTIN (angs, moeilike slaap, siek voel, pyn, sweet);
- Veranderinge in bloedtoetsresultate (kreatinien fosfokinase verhoog);
- Afbraak van spierweefsels (rabdomiolise);
- Probleme met abnormale/ onwillekeurige bewegings soos kronkeling, ruk, bewegings en styfheid;
- Selfmoord idees en gedrag;
- Hallusinasies;
- Afhanklik raak van BIOTECH GABAPENTIN ('medisyneafhanklikheid')'
- Akute nierversaking, inkontinensie;
- Vergrote borsweefsel, borsvergroting;
- Probleme met seksuele funksionering insluitend onvermoë om 'n seksuele klimaks te bereik, vertraagde ejakulasie.

Indien jy enige newe-effekte opmerk wat nie in hierdie pamflet genome word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien jy newe-effekte het, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aanmeld aan SAHPRA deur die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan jy help om meer inligting oor die veiligheid van BIOTECH GABAPENTIN te verskaf.

5. Hoe om BIOTECH GABAPENTIN te bewaar

Bewaar teen of benede 25 °C in 'n droë plek.
Bewaar alle medisyne buite bereik van kinders.
Moenie die kapsules gebruik na die datum wat op die karton gedruk is nie.
Gee alle ongebruikte medisyne terug aan jou apteker.
Moenie ongebruikte medisyne in dreine of rioolpype (bv toilette) weggooi nie.

6. Inhoud van die pakkie en ander inligting

Wat BIOTECH GABAPENTIN bevat:

Die aktiewe bestanddeel is gabapentien.
Die ander bestanddele is laktosemonohidraat, mieliestysel, gesuiwerde talk. Die kapsule bestaan uit gelatien en kleurstowwe (titaandioksied, rooi ysteroksied en geel ysteroksied).

Hoe BIOTECH GABAPENTIN lyk en die inhoud van die pak

BIOTECH GABAPENTIN 100: Groote 3 harde gelatienkapsule met 'n wit liggaam en 'n wit doppie wat wit kristallyne poeier bevat.
BIOTECH GABAPENTIN 300: Grootte 1 harde gelatienkapsule met 'n geel liggaam en 'n geel doppie wat wit kristallyne poeier bevat.
BIOTECH GABAPENTIN 400: Grootte 0 harde gelatienkapsule met 'n oranje liggaam en 'n oranje doppie wat wit kristallyne poeier bevat.

BIOTECH GABAPENTIN 100: Deurskynende PVC en gedrukte aluminiumfoelie stulpstroke wat 10 kapsules bevat en in 'n buitenste karton gepak is wat 100 kapsules bevat.
BIOTECH GABAPENTIN 300: Deurskynende PVC en gedrukte aluminiumfoelie stulpstroke wat 10 kapsules bevat en in 'n buitenste karton gepak is wat 100 kapsules bevat.
BIOTECH GABAPENTIN 400: Deurskynende PVC en gedrukte aluminiumfoelie stulpstroke wat 10 kapsules bevat en in 'n buitenste karton gepak is wat 100 kapsules bevat.

Houer van die sertifikaat van registrasie

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

Hierdie pamflet is die laaste hersien

08 Maart 2023

Registrasienommer

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