PREGABALIN BIOTECH

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

PREGABALIN 25 BIOTECH hard capsules
PREGABALIN 75 BIOTECH hard capsules
PREGABALIN 150 BIOTECH hard capsules
Pregabalin.
Sugar free.

Read all of this leaflet carefully before you start taking PREGABALIN BIOTECH.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare professional.
- PREGABALIN 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.

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

1. What PREGABALIN BIOTECH is and what it is used for

PREGABALIN BIOTECH is used to treat peripheral neuropathic pain (long-lasting pain caused by damage to the nerves), due to diabetes or shingles in adults.

2. What you need to know before you take PREGABALIN BIOTECH

Do not take PREGABALIN BIOTECH:
- if you are allergic (hypersensitive) to pregabalin or any of the other ingredients of PREGABALIN BIOTECH (listed in section 6).

Warnings and precautions:

Take special care with PREGABALIN BIOTECH:
- If you have diabetes and gain weight while you are taking PREGABALIN BIOTECH, your doctor may need to make a change in your diabetic medicines.
- If you experience an allergic reaction while you are taking PREGABALIN BIOTECH, you must contact your doctor immediately. The symptoms of an allergic reaction include swelling of the face, lips, tongue, and throat, as well as a skin rash.
- If you take PREGABALIN BIOTECH you may experience dizziness, sleepiness, loss of consciousness, confusion, and mental impairment. This could increase the possibility of an accidental injury (fall) if you are an elderly patient. Therefore, you should be careful until you are used to any effect caused by PREGABALIN BIOTECH.
- If you take PREGABALIN BIOTECH you may experience blurring or loss of vision, or other changes in eyesight, many of which are temporary. You should immediately tell your doctor if you experience any changes in your vision.
- If you notice a decrease in passing urine while taking PREGABALIN BIOTECH, you should tell your doctor. It may improve if you stop taking PREGABALIN BIOTECH.
- If you are taking PREGABALIN BIOTECH, or shortly after stopping it, you may experience convulsions (including epilepsy). If this happens, contact your doctor immediately. You may also experience withdrawal symptoms after short-term or long-term treatment with PREGABALIN BIOTECH, which include difficulty in sleeping, headache, nausea, anxiety, diarrhoea, flu syndrome, nervousness, depression, pain, hyperhidrosis and dizziness.
- If you have a history of a heart disease you should tell your doctor. Heart failure has been reported in some patients when they were taking PREGABALIN BIOTECH.
- If you are taking medicines for spinal cord injury, you may experience an increase in certain side effects such as sleepiness, when you are also taking PREGABALIN BIOTECH.
- Some people have had thoughts to harm or kill themselves while taking medicines belonging to the same group as PREGABALIN BIOTECH for the treatment of different conditions. If you have thoughts of harming or killing yourself, at any time when you are taking PREGABALIN BIOTECH, immediately contact your doctor.
- When PREGABALIN BIOTECH is taken with other medicines that may cause constipation (such as some types of pain medicines) it is possible that gastrointestinal problems may occur (e.g. constipation, blocked or paralysed bowel). Tell your doctor if you experience constipation, especially if you are prone to this problem.
- If you have a history of alcoholism or substance abuse or dependence, you should tell your doctor. If you think you need more PREGABALIN BIOTECH than prescribed, tell your doctor.
- If you have a history of any serious medical conditions, you should tell your doctor. There have been reports of reduction in brain function (encephalopathy) in some patients when they were taking PREGABALIN BIOTECH.
- There have been reports of breathing difficulties with PREGABALIN BIOTECH. If you have nervous system disorders, respiratory (breathing) disorders, renal (kidney) impairment, or you are older than 65, your doctor may prescribe a different dosing regimen for you. Contact your doctor if you experience trouble breathing or shallow breaths.

If you are not sure whether any of the above applies to you, ask your pharmacist of your doctor.

Other medicines and PREGABALIN BIOTECH:

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

PREGABALIN BIOTECH and certain other medicines may influence each other (interaction). When taken with certain other medicines, PREGABALIN BIOTECH may potentiate the side effects seen with these medicines, including respiratory failure and coma. The degree of dizziness, sleepiness and decreased concentration may be increased if PREGABALIN BIOTECH is taken together with medicines containing:
- Oxycodone (for treatment of pain)
- Lorazepam (for treatment of anxiety)
- Alcohol
- Opioids (for treatment of pain).

PREGABALIN BIOTECH may be taken with oral contraceptives.

PREGABALIN BIOTECH with food, drink and alcohol:

PREGABALIN BIOTECH may be taken with or without food.
It is advised not to drink alcohol while you are taking PREGABALIN BIOTECH.

Pregnancy, breastfeeding and fertility:

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking PREGABALIN BIOTECH.
PREGABALIN BIOTECH should not be taken during pregnancy or when breastfeeding. Effective contraception must be used by women of child-bearing potential.

Driving and using machines:

PREGABALIN BIOTECH may cause dizziness, sleepiness and decreased concentration. Head and body injuries and road traffic incidents have also been reported with PREGABALIN BIOTECH. You should not drive, operate machinery or engage in other potentially hazardous activities until you know whether PREGABALIN BIOTECH affects your ability to perform these activities.

3. How to take PREGABALIN BIOTECH

Do not share medicines prescribed for you with any other person.
Always take PREGABALIN BIOTECH exactly as your doctor has told you. Check with your doctor if you are not sure.
Your doctor will determine what dose is appropriate for you.
The usual dose is: 75 mg twice daily, (150 mg/day), with or without food. Based on individual patient response and tolerability, the dose may be increased to 150 mg twice daily after an interval of 3 to 7 days.
PREGABALIN BIOTECH is a long-term treatment and you may need to take it for some time. Your doctor will tell you how long your treatment with PREGABALIN BIOTECH will last.
PREGABALIN BIOTECH is for oral use only. PREGABALIN BIOTECH is taken orally with or without food. Swallow the capsule whole with water.
If you have the impression that the effect of PREGABALIN BIOTECH is too strong or too weak, tell your doctor or pharmacist.

Children and adolescents:

The safety and efficacy in children and adolescents (under 18 years of age) has not been established and therefore PREGABALIN BIOTECH should not be given to patients in this age group.

Kidney disorders:

Your doctor may prescribe a different dosing schedule and/ or dose.

Elderly patients:

If you are an elderly patient (over 65 years of age), you should take PREGABALIN BIOTECH normally except if you have problems with your kidneys. Discuss with your doctor.

If you take more PREGABALIN BIOTECH than you should:

In the event of overdosage, consult your doctor or pharmacist, if neither is available, contact the nearest hospital or poison centre. You may feel sleepy, confused, agitated, or restless as a result of taking more PREGABALIN BIOTECH than you should. Fits have also been reported.

If you forget to take PREGABALIN BIOTECH:

It is important to take your PREGABALIN BIOTECH capsules regularly at the same time each day. If you forget to take a dose, take it as soon as you remember, unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with PREGABALIN BIOTECH is stopped:

Do not stop taking PREGABALIN BIOTECH unless your doctor tells you to. If your treatment is stopped it should be done gradually over a minimum of one week.

4. Possible side effects

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

If any of the following happens, stop taking PREGABALIN 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,
- symptoms of respiratory problems, which can be life-threatening, such as 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 PREGABALIN 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:
- heart disorders including heart failure, heart rhythm disturbances, such as increased heart rate, irregular heartbeat,
- an extremely severe skin reaction with rash, ulcers or blisters on the skin (Stevens-Johnson syndrome),
- inflammation of the eyes (keratitis),
- urinary incontinence, difficulty in passing urine, kidney failure, passing small amounts of urine, urinary retention,
- inflammation of the liver (hepatitis),
- yellowing of the skin and eyes (jaundice).

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
- inflammation of nasal passages (common cold),
- increased appetite,
- feeling of elation, irritability and changes in sexual interest,
- sleepiness, headache,
- clumsiness, tremor, difficulty with speaking, forgetfulness, loss of memory, disturbance in attention, numbness or 'pins and needles', abnormally decreased sensitivity to stimulation,
- sedation, abnormal style of walking (balance disorder), lack of energy,
- blurred vision, double vision,
- sensation of movement,
- vomiting, nausea, constipation, diarrhoea, feeling bloated, abdominal distension, dry mouth,
- muscle cramp, pain in a joint, back pain, pain in a limb, cervical spasm,
- difficulties with erection,
- swelling of feet and lower legs caused by fluid retention, abnormal manner of walking, falling, feeling drunk, abnormal feeling, tiredness,
- weight gain.

Less frequently side effects
- reduced numbers of white blood cells which may make you more likely to get infections (neutropaenia),
- loss of appetite, low blood sugar,
- seeing or hearing things that are not there, panic attacks, restlessness, exceeding restlessness, depression, depressed mood, elevated mood, aggression, mood swings, change in perception of self (depersonalisation), difficulty speaking, abnormal dreams, lack of feeling or emotion, loss of inhibition,
- fainting, numbness, contraction of a muscle, loss of consciousness, jerky movements, difficulty of movement, dizziness on standing, tremor on movement, unusual eye movement, decreased consciousness, difficulty with thinking, speech disorder, reduced reflexes, increased sensitiveness of the skin, burning sensation, loss of taste, feeling of bodily discomfort, convulsions, perversion of the sense of smell, partial or complete loss of muscle movement, inability to write coherently, as a symptom of brain disease or damage,
- vision loss, peripheral vision loss, visual disturbance, eye swelling, visual field defect, reduced visual sharpness, eye pain, eye condition that manifests itself through nonspecific symptoms such as fatigue, pain in or around the eyes, the presence of flashes of light, dry eyes, watery eyes, eye irritation,
- visual field disturbance, altered visual depth perception, abnormal dilation of the pupil, squinting of eye(s), visual brightness,
- increased sensitivity to sound,
- low blood pressure, high blood pressure, hot flushes, redness of the neck and face, feeling cold,
- shortness of breath, nosebleed, cough, blocked nose, runny nose, snoring, nasal dryness, fluid in the lungs, tightness of the throat,
- heartburn, increased saliva production, numbness around the mouth, abdominal swelling, inflammation of the pancreas, swollen tongue, difficulty in swallowing,
- hives, excessive sweating, itching of the skin, cold sweat,
- joint swelling, pain in a muscle or muscles, muscle twitching, neck pain, muscle stiffness, breakdown of muscle tissue,
- problems with sexual functioning including inability to achieve a sexual climax, increased libido, difficulties with erection, delayed ejaculation, painful menstrual periods, breast pain, absence of menstrual period, breast discharge, breast enlargement, breast enlargement in men,
- generalised swelling caused by fluid retention, swelling of the face, chest tightness, pain, fever, thirst, chills, weakness,
- changes in blood and liver test results (increased blood creatinine phosphokinase, increased alanine amino transferase, increased blood glucose, increased aspartate aminotransferase, decreased platelet count, increased blood creatinine, decreased blood potassium, decreased white blood cell count).

Frequency unknown side effects
- thoughts of harming or killing one-self.

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 or pharmacist. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form"**, found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of PREGABALIN BIOTECH.

5. How to store PREGABALIN BIOTECH
- Store at or below 25 °C.
- Keep in the outer container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the label or carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What PREGABALIN BIOTECH contains

PREGABALIN 25 BIOTECH: Each hard capsule contains 25 mg pregabalin.
PREGABALIN 75 BIOTECH: Each hard capsule contains 75 mg pregabalin.
PREGABALIN 150 BIOTECH: Each hard capsule contains 150 mg pregabalin.

The other ingredients are:

Capsule content
Pregelatinised starch
Talcum
Capsule shell
Gelatine
Titanium dioxide (E171)
Printing ink
Black iron oxide (E172)
Potassium hydroxide
Propylene glycol
Shellac.

What PREGABALIN BIOTECH looks like and contents of the pack

PREGABALIN 25 BIOTECH : Opaque white/ opaque white, size '4', hard gelatine capsules, radially imprinted with 'PG' on cap and '25' on body with black ink, filled with white to off -white powder.
PREGABALIN 75 BIOTECH: Opaque white/ orange opaque, size '4', hard gelatine capsules, radially imprinted with 'PG' on cap and '75' on body with black ink, filled with white to off -white powder.
PREGABALIN 150 BIOTECH: Opaque white/ opaque white, Size '2', hard gelatine capsules, radially imprinted with 'PG' on cap and '150' on body with black ink, filled with white to off -white powder.
White HDPE round bottles with a child resistant cap or a screw cap, containing 30 or 1000 capsules OR a PVC/aluminium blister strip containing 10 capsules, packed in an outer carton.
Not all packaging types and/ or pack sizes may be marketed at the same time.

Holder of certificate of registration

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PREGABALIN 75 BIOTECH: 50/2.5/0372
PREGABALIN 150 BIOTECH: 50/2.5/0373

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08 March 2022

PREGABALIN BIOTECH

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS
S5

PREGABALIN 25 BIOTECH harde kapsules
PREGABALIN 75 BIOTECH harde kapsules
PREGABALIN 150 BIOTECH harde kapsules
Pregabalien.
Suikervry.

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

Wat is in hierdie pamflet

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

1. Wat PREGABALIN BIOTECH is en waarvoor dit gebruik word
PREGABALIN BIOTECH word gebruik vir die behandeling van perifere neuropatiese pyn (langdurige pyn wat veroorsaak word deur skade aan die senuwees), as gevolg van diabetes of gordelroos by volwassenes.

2. Wat jy moet weet voordat jy PREGABALIN BIOTECH neem
Moenie PREGABALIN BIOTECH neem nie:
- indien jy allergies (hipersensitief) is vir pregabalien of vir enige van die ander bestanddele van PREGABALIN BIOTECH (gelys in afdeling 6).

Waarskuwings en voorsorgmaatreëls:
Neem spesiale sorg met PREGABALIN BIOTECH:
- Indien jy diabetes het en gewig optel terwyl jy PREGABALIN BIOTECH neem, sal jou dokter dalk 'n verandering in jou diabetiese medisyne moet maak.
- Indien jy 'n allergiese reaksie ervaar terwyl jy PREGABALIN BIOTECH neem, moet jy dadelik jou dokter kontak. Die simptome van 'n allergiese reaksie sluit in swelling van die gesig, lippe, tong en keel, sowel as 'n veluitslag.
- Indien jy PREGABALIN BIOTECH neem, kan jy duiseligheid, slaperigheid, bewussynsverlies, verwarring en verstandelike gestremdheid ervaar. Dit kan die moontlikheid van 'n toevallige besering (val) verhoog as jy 'n bejaarde pasiënt is. Daarom moet jy versigtig wees totdat jy gewoond is aan enige effek wat deur PREGABALIN BIOTECH veroorsaak word.
- Indien jy PREGABALIN BIOTECH neem, kan jy vervaagde of verlies van sig ervaar, of ander veranderinge in sig, waarvan baie tydelik is. Jy moet dadelik jou dokter vertel as jy enige veranderinge in jou visie ervaar.
- Indien jy 'n afname in urinering sien terwyl jy PREGABALIN BIOTECH neem, moet jy jou dokter vertel. Dit kan verbeter as jy ophou om PREGABALIN BIOTECH te neem.
- Indien jy PREGABALIN BIOTECH neem, of kort nadat jy dit gestaak het, kan jy stuiptrekkings ervaar (insluitend epilepsie). Indien dit gebeur, kontak jou dokter dadelik. Jy kan ook onttrekkingsimptome ervaar na korttermyn- of langtermynbehandeling met PREGABALIN BIOTECH, wat slaapprobleme, hoofpyn, naarheid, angs, diarree, griepsindroom, senuweeagtigheid, depressie, pyn, hiperhidrose en duiseligheid insluit.
- Indien jy 'n geskiedenis van 'n hartsiekte het, moet jy jou dokter vertel. Hartversaking is by sommige pasiënte aangemeld toe hulle PREGABALIN BIOTECH geneem het.
- Indien jy medisyne vir rugmurgbesering neem, kan jy 'n toename in sekere newe-effekte soos slaperigheid ervaar wanneer jy ook PREGABALIN BIOTECH neem.
- Sommige mense het gedagtes gehad om hulself te benadeel of dood te maak terwyl hulle medisyne geneem het wat aan dieselfde groep as PREGABALIN BIOTECH behoort vir die behandeling van verskillende toestande. As jy gedagtes het om jouself te beseer of dood te maak, te eniger tyd wanneer jy PREGABALIN BIOTECH neem, kontak dadelik jou dokter.
- Wanneer PREGABALIN BIOTECH saam met ander medisyne geneem word wat hardlywigheid kan veroorsaak (soos sommige tipes pynmedisyne), is dit moontlik dat gastroïntestinale probleme kan voorkom (bv. hardlywigheid, verstopte of verlamde derm). Vertel jou dokter as jy hardlywigheid ervaar, veral as jy geneig is tot hierdie probleem.
- Indien jy 'n geskiedenis van alkoholisme of dwelmmisbruik of afhanklikheid het, moet jy jou dokter vertel. As jy dink jy benodig meer PREGABALIN BIOTECH as wat voorgeskryf is, vertel jou dokter.
- Indien jy 'n geskiedenis van enige ernstige mediese toestande het, moet jy jou dokter vertel. Daar is berigte van vermindering in breinfunksie (enkefalopatie) by sommige pasiënte toe hulle PREGABALIN BIOTECH geneem het.
- Daar was berigte van asemhalingsprobleme met PREGABALIN BIOTECH. As jy senuweestelselafwykings, respiratoriese (asemhalings-) versteurings, nier- (renale) inkorting het, of jy is ouer as 65, kan jou dokter 'n ander doseringsregime vir jou voorskryf.

Kontak jou dokter as jy sukkel om asem te haal of vlak asem te haal.
Indien jy nie seker is of enige van die bogenoemde op jou van toepassing is nie, vra jou apteker of jou dokter.

Ander medisyne en PREGABALIN BIOTECH:
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit alle Komplementêre of tradisionele medisyne in.)
PREGABALIN BIOTECH en sekere ander medisyne kan mekaar beïnvloed (interaksie). Wanneer dit saam met sekere ander medisyne geneem word, kan PREGABALIN BIOTECH die newe-effekte wat met hierdie medisyne gesien word, insluitend respiratoriese versaking en koma versterk. Die graad van duiseligheid, slaperigheid en verminderde konsentrasie kan verhoog word as PREGABALIN BIOTECH saam met die volgende medisyne geneem word:
- Oksikodoon (vir die behandeling van pyn)
- Lorasepam (vir die behandeling van angstigheid)
- Alkohol
- Opioïede (vir die behandeling van pyn).

PREGABALIN BIOTECH mag saam met orale voorbehoedmiddels geneem word.

PREGABALIN BIOTECH met kos, drank en alkohol:
PREGABALIN BIOTECH kan met of sonder kos geneem word.
Dit word aangeraai om nie alkohol te drink terwyl jy PREGABALIN BIOTECH neem nie.

Swangerskap, borsvoeding en vrugbaarheid:
Indien jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, vra jou dokter of apteker vir advies voordat jy PREGABALIN BIOTECH neem.
PREGABALIN BIOTECH moet nie tydens swangerskap of tydens borsvoeding geneem word nie. Doeltreffende voorbehoedmiddels moet deur vroue met vrugbare potensiaal gebruik word.

Bestuur en die gebruik van masjiene:
PREGABALIN BIOTECH kan duiseligheid, slaperigheid en verminderde konsentrasie veroorsaak. Hoof- en liggaamsbeserings en padverkeersvoorvalle is ook met PREGABALIN BIOTECH aangemeld. Jy moenie bestuur, masjinerie gebruik of aan ander potensieel gevaarlike aktiwiteite deelneem totdat jy weet of PREGABALIN BIOTECH jou vermoë om hierdie aktiwiteite uit te voer, beïnvloed nie.

3. Hoe om PREGABALIN BIOTECH te neem
Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd PREGABALIN BIOTECH presies soos jou dokter vir jou gesê het. Raadpleeg met jou dokter as jy nie seker is nie.
Jou dokter sal bepaal watter dosis geskik is vir jou.
Die gewone dosis is: 75 mg twee keer per dag, (150 mg/dag), met of sonder kos. Gebaseer op individuele pasiënt reaksie en verdraagsaamheid, kan die dosis verhoog word tot 150 mg twee keer per dag na 'n interval van 3 tot 7 dae.
PREGABALIN BIOTECH is 'n langtermynbehandeling en jy sal dit dalk vir 'n geruime tyd moet neem. Jou dokter sal jou vertel hoe lank jou behandeling met PREGABALIN BIOTECH sal duur.
PREGABALIN BIOTECH is slegs vir orale gebruik. PREGABALIN BIOTECH word mondelings met of sonder kos ingeneem. Sluk die kapsule heel met water.
As jy die indruk het dat die effek van PREGABALIN BIOTECH te sterk of te swak is, vertel jou dokter of apteker.

Kinders en adolessente:
Die veiligheid en doeltreffendheid by kinders en adolessente (jonger as 18 jaar oud) is nie vasgestel nie en daarom moet PREGABALIN BIOTECH nie aan pasiënte in hierdie ouderdomsgroep gegee word nie.

Nierversteurings:
Jou dokter kan 'n ander doseringskedule en/ of dosis voorskryf.

Bejaarde pasiënte:
As jy 'n bejaarde pasiënt (ouer as 65 jaar oud) is, kan jy PREGABALIN BIOTECH normaalweg neem, behalwe as jy probleme met jou niere het. Bespreek met jou dokter.

Indien jy meer PREGABALIN BIOTECH neem as wat jy moet:
In die geval van oordosering, raadpleeg jou dokter of apteker, indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum. Jy mag dalk slaperig, verward, opgewonde of rusteloos voel as gevolg van die neem van meer PREGABALIN BIOTECH as wat jy behoort te neem. Stuiptrekkings is ook aangemeld.

Indien jy vergeet om PREGABALIN BIOTECH te neem:
Dit is belangrik om jou PREGABALIN BIOTECH-kapsules gereeld op dieselfde tyd elke dag te neem. As jy vergeet om 'n dosis te neem, neem dit so gou as wat jy onthou, tensy dit tyd is vir jou volgende dosis. In daardie geval, gaan net voort met die volgende dosis soos normaal. Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

Effekte wanneer behandeling met PREGABALIN BIOTECH gestaak word:
Moenie ophou om PREGABALIN BIOTECH te neem nie, tensy jou dokter jou beveel om dit te doen. As jou behandeling gestaak word, moet dit geleidelik oor 'n minimum van een week gedoen word.

4. Moontlike newe-effekte
PREGABALIN BIOTECH kan newe-effekte hê.
Nie alle newe-effekte wat vir PREGABALIN BIOTECH aangemeld is, is in hierdie pamflet ingesluit nie. Indien jou algemene gesondheid versleg of as jy enige nadelige effekte ervaar terwyl jy PREGABALIN BIOTECH neem, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om PREGABALIN BIOTECH te neem en vertel jou dokter dadelik of gaan na die ongevalle-afdeling van jou naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- veluitslag of jeuk,
- simptome van respiratoriese probleme, wat lewensgevaarlik kan wees, soos verwarring of disoriëntasie, ongewone duiseligheid of lighoofdigheid, uiterste slaperigheid of lusteloosheid, vertraagde, vlak of moeilike asemhaling, onreaksie, wat beteken dat 'n persoon nie antwoord of normaal reageer nie of jy kan hulle nie wakker maak nie, blouerige of getinte vel, veral op die lippe, vingers en tone.

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

Vertel jou dokter dadelik of gaan na die ongevalle-afdeling van jou naaste hospitaal indien jy enige van die volgende opmerk:
- hartversteurings insluitend hartversaking, hartritme versteurings, soos verhoogde hartklop, onreëlmatige hartklop,
- 'n uiters ernstige velreaksie met uitslag, ulkusse of blase op die vel (Stevens Johnson se sindroom),
- inflammasie van die oë (keratitis),
- urinêre inkontinensie, probleme met urinering, nierversaking, klein hoeveelhede urine, urinêre retensie,
- inflammasie van die lewer (hepatitis),
- vergeling van die vel en oë (geelsug).

Hierdie is almal baie ernstige newe-effekte. Jy mag dalk dringende mediese aandag benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Gereelde newe-effekte:
- inflammasie van neuskanale (verkoue),
- verhoogde eetlus,
- gevoel van opgewondenheid, prikkelbaarheid, en veranderinge in seksuele belangstelling,
- slaperigheid, hoofpyn,
- lompheid, bewing, probleme met praat, vergeetagtigheid, geheueverlies, aandagversteuring, gevoelloosheid of 'spelde en naalde', abnormale verminderde sensitiwiteit vir stimulasie,
- sedasie, abnormale loopstyl (balansversteuring), gebrek aan energie,
- versteurde visie, dubbelvisie,
- sensasie van beweging,
- braking, naarheid, hardlywigheid, diarree, opgeblase gevoel, abdominale distensie, droë mond,
- spierkrampe, pyn in 'n gewrig, rugpyn, pyn in 'n ledemaat, servikale spasma,
- probleme met ereksie,
- swelling van voete en onderbene veroorsaak deur vloeistofretensie, abnormale manier van loop, val, dronk voel, abnormale gevoel, moegheid,
- gewigstoename.

Minder algemene newe-effekte
- verminderde aantal witbloedselle wat jou meer geneig kan maak om infeksies te kry (neutropenie),
- verlies aan eetlus, lae bloedsuiker,
- dinge sien of hoor wat nie daar is nie, paniekaanvalle, rusteloosheid, oormatige rusteloosheid, depressie, depressiewe bui, verhoogde bui, aggressie, gemoedskommelings, verandering in persepsie van self (depersonalisering), probleme met praat, abnormale drome, gebrek aan gevoel of emosie, verlies van inhibisie,
- floute, gevoelloosheid, sametrekking van 'n spier, verlies van bewussyn, rukkerige bewegings, moeilike bewegings, duiseligheid wanneer jy staan, bewing tydens beweging, ongewone oogbewegings, verminderde bewussyn, probleme met dink, spraakversteuring, verminderde reflekse, verhoogde sensitiwiteit van die vel, brandende sensasie, smaakverlies, gevoel van liggaamlike ongemak, stuiptrekkings, verandering van die reuksintuig, gedeeltelike of algehele verlies van spierbeweging, onvermoë om samehangend te skryf, as 'n simptoom van breinsiekte of skade,
- sigverlies, perifere sigverlies, visuele versteuring, oogswelling, sigvelddefek, verminderde visuele skerpte, oogpyn, oogtoestand wat manifesteer deur nie-spesifieke simptome soos moegheid, pyn in of om die oë, die teenwoordigheid van ligflitse, droë oë, waterige oë, oogirritasie,
- visuele veldversteuring, veranderde visuele dieptepersepsie, abnormale verwyding van die pupil, skeel oog/ oë, visuele helderheid,
- verhoogde sensitiwiteit vir klank,
- lae bloeddruk, hoë bloeddruk, warm gloede, rooiheid van die nek en gesig, koud voel,
- kortasem, neusbloeding, hoes, verstopte neus, loopneus, snork, nasale droogheid, vloeistof in die longe, toetrek van die keel,
- sooibrand, verhoogde speekselproduksie, gevoelloosheid rondom die mond, abdominale swelling, ontsteking van die pankreas, geswelde tong, probleme om te sluk,
- velbulte, oormatige sweet, jeuk van die vel, koue sweet,
- gewrigsswelling, pyn in 'n spier of spiere, spiertrekkings, nekpyn, spierstyfheid, afbreek van spierweefsel,
- probleme met seksuele funksionering insluitend onvermoë om 'n seksuele klimaks te bereik, verhoogde libido, probleme met ereksie, vertraagde ejakulasie, pynlike menstruasieperiodes, borspyn, afwesigheid van menstruasieperiode, borsafskeiding, borsvergroting, borsvergroting by mans,
- algemene swelling wat veroorsaak word deur vloeistofretensie, swelling van die gesig, stywe bors, pyn, koors, dors, koue rillings, swakheid,
- veranderinge in bloed- en lewertoetsresultate (verhoogde bloed kreatinienfosfokinase, verhoogde alanienaminotransferase, verhoogde bloedglukose, verhoogde aspartaataminotransferase, verlaagde bloedplaatjietelling, verhoogde bloedkreatinien, verlaagde bloedkalium, verlaagde witbloedseltelling).

Newe-effekte met onbekende frekwensie
- gedagtes om jouself te beseer of dood te maak.

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

Aanmelding van newe-effekte
As jy newe-effekte kry, praat met jou dokter of apteker. Jy kan ook newe-effekte aan SAHPRA rapporteer via die vorm **"6.04 Adverse Drug Reactions Reporting Form"**, wat aanlyn gevind word onder SAHPRA se publikasies: http://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van PREGABALIN BIOTECH te verskaf.

5. Hoe om PREGABALIN BIOTECH te bewaar
- Bewaar teen of benede 25 °C.
- Hou in die buitenste houer tot dit benodig word vir gebruik.
- Bewaar alle medisyne buite bereik van kinders.
- Moet nie gebruik na die vervaldatum wat op die etiket of karton gedruk is nie.
- Gee alle ongebruikte medisyne terug aan jou apteker.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting
Wat PREGABALIN BIOTECH bevat
PREGABALIN 25 BIOTECH: Elke harde kapsule bevat 25 mg pregabalien.
PREGABALIN 75 BIOTECH: Elke harde kapsule bevat 75 mg pregabalien.
PREGABALIN 150 BIOTECH: Elke harde kapsule bevat 150 mg pregabalien.

Die ander bestanddele is:
Kapsule inhoud
Voorgegelatineerde stysel
Talk
Kapsule dop
Gelatien
Titaandioksied (E171)
Drukink
Swart ysteroksied (E172)
Kaliumhidroksied
Propileenglikol
Shellak.

Hoe PREGABALIN BIOTECH lyk en inhoud van die verpakking
PREGABALIN BIOTECH 25: Ondeursigtige wit/ ondeursigtige wit, grootte '4', harde gelatienkapsules, radiaal gedruk met 'PG' op die dop en '25' op die lyf met swart ink, gevul met wit tot naaswit poeier.
PREGABALIN BIOTECH 75: Ondeursigtig wit/ ondeursigtige oranje, grootte '4', harde gelatienkapsules, radiaal gedruk met 'PG' op die dop en '75' op die lyf met swart ink, gevul met wit tot naaswit poeier.
PREGABALIN BIOTECH 150: Ondeursigtige wit/ ondeursigtige wit, grootte '2', harde gelatienkapsules, radiaal gedruk met 'PG' op die dop en '150' op die lyf met swart ink, gevul met wit tot naaswit poeier.
Wit HDPE ronde bottels met 'n kinderbestande doppie, wat 30 of 1000 kapsules bevat OF 'n PVC/aluminium stulpstrook wat 10 kapsules bevat, verpak in 'n buitekarton.
Nie alle verpakkingstipes en/ of pakgroottes mag bemark word op dieselfde tyd nie.

Houer van die sertifikaat van registrasie

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011 848 3050

Hierdie pamflet is laas hersien
06 Julie 2023

Registrasienommers
PREGABALIN 25 BIOTECH: 50/2.5/0371
PREGABALIN 75 BIOTECH: 50/2.5/0372
PREGABALIN 150 BIOTECH: 50/2.5/0373

Datum van registrasie
08 Maart 2022