BIOTECH GABAPENTIN 100; 300 & 400
capsules (43/2.5/0332; 43/2.5/0329; 43/2.5/0333)
Each capsule contains gabapentin 100 mg, 300 mg or 400 mg respectively

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 each 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 belongs to a group of medicines used to treat epilepsy.

BIOTECH GABAPENTIN is used to treat various forms of epilepsy. Your doctor will prescribe BIOTECH GABAPENTIN if your current treatment is no longer fully controlling your epilepsy. You should take BIOTECH GABAPENTIN in addition to your current treatment. If your doctor considers that it is necessary, BIOTECH GABAPENTIN can also be used on its own.

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;
- you have severe reduced kidney function.

Warnings and precautions

Take special care with BIOTECH GABAPENTIN:

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. Stop taking BIOTECH GABAPENTIN and seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in 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.

- 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, breastfeeding and fertility

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.

Do not take BIOTECH GABAPENTIN during pregnancy (see section 2, Do not take BIOTECH

GABAPENTIN).

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.

Do 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 breastfeed while taking BIOTECH GABAPENTIN.

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 some 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;
- purple spots on the skin;
- 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 on 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;
- red spots and tiny bumps on your skin that may be itchy;
- 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);
- suicidal ideation and behaviour;
- becoming dependent on BIOTECH GABAPENTIN (‘medicine dependence’);
- decreased movement, mental impairment; loss of consciousness;
- problems with abnormal/ involuntary movements such as writhing, jerking, movements and stiffness;
- 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); sudden, quick muscle jerks or twitches
- spastic torticollis (disorder where the muscles of the neck contract uncontrollably, making the head
- hallucinations;
- 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. 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 ºC 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

400 16th Road

Ground Floor, Block K West, Central Park

Randjespark

Midrand,

Gauteng**,** 6185

Tel: 011 848 3050

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BIOTECH GABAPENTIN 100: 43/2.5/0332

BIOTECH GABAPENTIN 300: 43/2.5/0329

BIOTECH GABAPENTIN 400: 43/2.5/0333

Access to the corresponding Professional Information

The Professional Information Leaflet is available from Biotech Laboratories (Pty) Ltd. To request a digital copy, please email info@biotechlabs.co.za.