

Patient Information Leaflet for LEVETIRACETAM BIOTECH**PATIENT INFORMATION LEAFLET****SCHEDULING STATUS****S3****LEVETIRACETAM 250 BIOTECH film-coated tablets****LEVETIRACETAM 750 BIOTECH film-coated tablets****LEVETIRACETAM 1000 BIOTECH film-coated tablets****Levetiracetam****Sugar free.****Read all of this leaflet carefully before you start taking LEVETIRACETAM BIOTECH:**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- LEVETIRACETAM 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 LEVETIRACETAM BIOTECH is and what it is used for
2. What you need to know before you take LEVETIRACETAM BIOTECH
3. How to take LEVETIRACETAM BIOTECH
4. Possible side effects
5. How to store LEVETIRACETAM BIOTECH

6. Contents of the pack and other information

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

LEVETIRACETAM BIOTECH is a medicine used to treat seizures in epilepsy.

LEVETIRACETAM BIOTECH is used alone in the treatment of partial onset seizures in patients from 16 years of age with newly diagnosed epilepsy.

LEVETIRACETAM BIOTECH is also used as an add-on to other anti-epileptic medicine:

- in the treatment of partial onset seizures with or without secondary generalisation in adults and children over 16 years of age with epilepsy
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
- in the treatment of primary generalised tonic-clonic seizures in adults and children from 16 years of age with idiopathic generalised epilepsy.

2. What you need to know before LEVETIRACETAM BIOTECH is administered to you**Do not take LEVETIRACETAM BIOTECH:**

- if you are hypersensitive (allergic) to levetiracetam, pyrrolidine derivatives or any of the other ingredients of LEVETIRACETAM BIOTECH (listed in section 6)
- if you are pregnant or breastfeeding your baby.

Warnings and precautions:

Drug reaction with eosinophilia and systemic symptoms (DRESS) has been reported with the use of LEVETIRACETAM BIOTECH. DRESS appears initially as flu-like symptoms and a rash on the face then an extended rash with a high body temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cell (eosinophilia) and enlarged lymph nodes. If you develop fever and enlarged lymph nodes, with or without the appearance of a rash, stop taking LEVETIRACETAM BIOTECH and contact your doctor or seek medical attention

immediately (see section 4).

Tell your doctor:

- if you have kidney or liver problems, tell your doctor. He/she may decide if your dose should be adjusted
- if you have any symptoms of depression and/or thoughts of harming or killing yourself (suicide), please contact your doctor
- if you experience weakness, fever, recurrent infections, your doctor may advise you to go for blood tests
- if you experience abnormal thoughts, feeling irritable or reacting more aggressively than usually, or if you or your family and friends notice important changes in mood or behaviour
- if you experience aggravation of epilepsy or worsening of seizures
- if you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances.

Children and adolescents:

LEVETIRACETAM BIOTECH have not been approved for children below the age of 12 years (see “What LEVETIRACETAM BIOTECH is and what it is used for”).

Other medicines and LEVETIRACETAM BIOTECH:

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

- Tell your doctor if you are using methotrexate (a medicine used in the treatment of cancer and to suppress the immune system).
- Do not take macrogol (a medicine used as laxative) for one hour before and one hour after

taking LEVETIRACETAM BIOTECH as this may result in a loss of its effect.

Pregnancy and breastfeeding:

Do not take LEVETIRACETAM BIOTECH when you are pregnant or suspect to be pregnant.

You should not breastfeed your baby if you are using LEVETIRACETAM BIOTECH.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking LEVETIRACETAM BIOTECH.

Driving and using machines:

LEVETIRACETAM BIOTECH may cause dizziness, headache and feeling sleepy and may impair your ability to drive or operate any tools or machinery. You should not drive or use machines until you are sure that your ability to perform such activities is not affected by LEVETIRACETAM BIOTECH.

3. How to take LEVETIRACETAM BIOTECH

Do not share medicines prescribed for you with any other person.

Always take LEVETIRACETAM BIOTECH exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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

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

The film-coated tablets must be taken orally (by mouth), swallowed with liquid and may be taken with or without food. LEVETIRACETAM BIOTECH must be taken twice a day, once in the morning and once in the evening, at about the same time each day. Take the number of tablets as indicated on the label.

- When LEVETIRACETAM BIOTECH is used alone

Adults and adolescents from 16 years of age:

The usual starting dose is 250 mg twice daily which may be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose may be further increased by 250 mg twice daily every two weeks depending upon the clinical response as determined by your doctor. The maximum daily dose is 1 500 mg twice daily. The dose specific for you, will be determined by your doctor and you should follow his / her instructions carefully.

- When LEVETIRACETAM BIOTECH is used in combination with other anti-epileptic medicine

Adults (18 years or older) and adolescents (12 to 17 years) weighing 50 kg or more:

The usual initial therapeutic dose is 500 mg twice daily. The dose can be started on the first day of treatment.

Depending upon the clinical response as determined by your doctor and how well you tolerate the medicine, the daily dose may be increased up to 1 500 mg twice daily. Dose changes may be made in 500 mg twice daily increases or decreases every two to four weeks. The dose specific for you, will be determined by your doctor and you should follow his / her instructions carefully.

Adolescents (12 to 17 years) weighing less than 50 kg:

The usual initial therapeutic dose is 10 mg/kg twice daily. This dose can be started on the first day of treatment.

Depending upon the clinical response as determined by your doctor and how well you tolerate the medicine, the dose may be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10 mg/kg twice daily every two weeks. The lowest effective dose should be used. The dose specific for you, will be determined by your doctor and you should follow his / her instructions carefully.

Duration of treatment:

LEVETIRACETAM BIOTECH is used as a chronic treatment. You should continue

LEVETIRACETAM BIOTECH treatment for as long as your doctor prescribes it for you.

Do not stop your treatment without your doctor's advice as this could increase your seizures.

If you take more LEVETIRACETAM BIOTECH than you should:

- In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison centre.
- Signs of taking too much LEVETIRACETAM BIOTECH are increased sleepiness, anxiety, decreased consciousness and difficulty in breathing.

If you forget to take LEVETIRACETAM BIOTECH:

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for forgotten individual doses.

If you stop taking LEVETIRACETAM BIOTECH:

If stopping treatment, LEVETIRACETAM BIOTECH should be discontinued gradually to avoid an increase of seizures.

Should your doctor decide to stop your LEVETIRACETAM BIOTECH treatment, he/she will instruct you about the gradual withdrawal of LEVETIRACETAM BIOTECH.

4. Possible side effects

LEVETIRACETAM BIOTECH can have side effects.

Not all side effects reported for LEVETIRACETAM BIOTECH are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking

LEVETIRACETAM BIOTECH, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop taking LEVETIRACETAM 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
- detachment of the top layers of your skin
- ulcers and other lesions on the mucous membranes in the mouth and lips accompanied by fever, sore throat and fatigue
- flu-like symptoms and a rash on the face followed by an extended rash with a high temperature, increased levels of liver enzymes seen in blood tests and an increase in a type of white blood cells (eosinophilia) and enlarged lymph nodes (see section Warnings and precautions).

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

- low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, as this may be a sign of sudden decrease of kidney function
- a skin rash which may form blisters and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge)
- signs of serious mental changes or if someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour or other neurological signs including involuntary or uncontrolled movements, as these could be symptoms of an encephalopathy
- suicide attempt and suicidal thoughts
- seizures (fits) may become worse or happen more often
- change of the heart rhythm

- yellowing of the skin and eyes, dark urine and tiredness which may be symptoms of liver problems (liver failure or hepatitis)
- inflammation of the pancreas (severe upper abdominal burning pain radiating to the back, nausea, and vomiting that is worsened with eating)
- breakdown of muscle tissue (rhabdomyolysis), causing dark, reddish urine, a decreased amount of urine, weakness and muscle aches.

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:

- feeling sleepy and tiredness, lack of energy
- headache
- nasopharyngitis (common cold)
- dizziness, balance disorder
- anxiety, depression, mood swings, aggression, sleeping problems, irritability, behavioural problems
- diarrhoea, indigestion, abdominal pain, nausea and vomiting
- loss of appetite, eating disorders (anorexia)
- vertigo (sensation of rotation)
- increase of pre-existing cough
- rash.

Other side effects that may occur less frequently reported with the use of LEVETIRACETAM BIOTECH:

- sensation of tingling, burning, prickling, tickling, or pricking of a person's skin
- disturbance in attention
- involuntary movements in a combination of irregular contractions and twisting and writing

- hyperactivity, impaired coordinated movements, involuntary trembling, loss of memory, memory impairment loss of concentration and forgetfulness
- anger, agitation, personality disorder
- increase weight, decrease weight
- confusion, hallucination (a false perception)
- double vision, blurred vision
- muscle pain or weakness
- hair loss, eczema, itching.

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 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 LEVETIRACETAM BIOTECH.

5. How to store LEVETIRACETAM BIOTECH

Keep your tablets in a safe place where children cannot see or reach them. Your tablets could harm them.

You should keep your tablets at or below 25 °C.

The blister strips must be kept in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN

If your doctor decides to stop your treatment, return any left-over tablets to your pharmacist.

You should not take the tablets after the expiry date on the container. Return all expired medicines to your pharmacist.

6. Contents of the pack and other information

What LEVETIRACETAM BIOTECH contains:

The active substance is levetiracetam.

Each LEVETIRACETAM BIOTECH tablet contains 250 mg or 750 mg or 1 000 mg levetiracetam, respectively.

The other ingredients are colloidal anhydrous silica, croscarmellose sodium, magnesium stearate, maize starch, povidone, talc.

LEVETIRACETAM 250 BIOTECH contains Opadry II blue (consisting of FD&C blue, indigo carmine aluminium lake, polyvinyl alcohol, macrogol, talc and titanium dioxide).

LEVETIRACETAM 750 BIOTECH contains Opadry II orange (consisting of FD&C yellow and sunset yellow, iron oxide red, polyvinyl alcohol, macrogol, talc and titanium dioxide).

LEVETIRACETAM 1000 BIOTECH Opadry II white (consisting of polyvinyl alcohol, macrogol, talc and titanium dioxide).

What LEVETIRACETAM BIOTECH looks like and contents of the pack:

LEVETIRACETAM 250 BIOTECH: Blue, oblong shaped scored film-coated tablet debossed with 'H' on one side and '87' on other side.

LEVETIRACETAM 750 BIOTECH: Orange coloured, oblong shaped, scored, film coated tablets debossed with 'H' on one side and '90' on other side.

LEVETIRACETAM 1000 BIOTECH: White, oblong shaped scored film-coated tablet debossed with 'H' on one side and '91' on other side.

LEVETIRACETAM BIOTECH tablets are packed in plain aluminium foil, clear PVC or clear PVC/PVdC blister strips. Each blister strip contains 10 tablets each. Three, five or ten blisters are packed in an outer carton.

Holder of certificate of registration and manufacturer:

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