PATIENT INFORMATION LEAFLET

DYNA LEVETIRACETAM RANGE

SCHEDULING STATUS

S3

DYNA LEVETIRACETAM 250 mg film coated tablets

DYNA LEVETIRACETAM 500 mg film coated tablets

DYNA LEVETIRACETAM 750 mg film coated tablets

Levetiracetam

DYNA LEVETIRACETAM tablets are sugar free.

Read all of this leaflet carefully before you start taking DYNA LEVETIRCETAM

- 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.
- DYNA LEVETIRACETAM 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 DYNA LEVETIRACETAM is and what it is used for

DYNA LEVETIRACETAM is an anti-epileptic medicine and is used alone to treat:

- seizures in adults and children over the age of 16 years, when epilepsy is diagnosed for the first time, or together with another anti-epileptic medicine
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
- primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 16 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

1. What you need to know before you take DYNA LEVETIRACETAM

Do not take DYNA LEVETIRACETAM:

- if you are hypersensitive (allergic) to levetiracetam, or to any of the ingredients of DYNA LEVETIRACETAM (see section 6)
- if you are pregnant, suspect you are pregnant or breastfeeding your baby.

Warnings and precautions

Take special care with DYNA LEVETIRACETAM:

- if you have thoughts of harming or killing yourself. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor immediately
- if you suffer from kidney problems, or receive dialysis, follow your doctor's instructions. He/she may decide that your dose should be adjusted
- if you have a severe liver disease
- if you suffer from high fever or recurring infections, or bleeding disorders, as the doctor may want to do blood tests and monitor your condition
- if you have abnormal thoughts, feel irritable or react more aggressively than usual, or if you or your family and friends notice important changes in mood or behaviour
- if you stop taking DYNA LEVETIRACETAM suddenly, you may have increased seizures. Tell your doctor if you have new or worsening seizures. Do not stop taking DYNA

LEVETIRACETAM without first talking to your doctor, even if you feel better (see Effects when treatment is stopped). DYNA LEVETIRACETAM should not be given to infants and children under the age of 12 years.

Other medicines and DYNA LEVETIRACETAM

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

- other anti-epileptic medicines (such as phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin and primidone), as they may affect the way DYNA LEVETIRACETAM works
- probenecid (a medicine used to increase uric acid excretion by the kidneys in patients with gout), as this may affect the way DYNA LEVETIRACETAM works
- methotrexate (a medicine used to treat certain types of cancer), as the use of DYNA LEVETIRACETAM may increase your blood levels of methotrexate.

Do not take macrogol (a medicine used as a laxative) for one hour before and one hour after taking DYNA LEVETIRACETAM, as this may result in a loss of its effect.

DYNA LEVETIRACETAM with food and drink

DYNA LEVETIRACETAM should be taken by mouth, swallowed with liquid and may be taken with or without food.

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 health care professional for advice before taking this medicine.

Do not take DYNA LEVETIRACETAM if you are pregnant or suspect that you are pregnant. Contact you doctor immediately.

Do not take DYNA LEVETIRACETAM if you are breastfeeding your baby (see Do not take Dyna Levetiracetam).

Driving and using machines

DYNA LEVETIRACETAM may make you feel sleepy or dizzy. It is not always possible to predict to what extent DYNA LEVETIRACETAM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DYNA LEVETIRACETAM affects them.

3. How to take DYNA LEVETIRACETAM

Do not share medicines prescribed for you with any other person. Always take DYNA LEVETIRACETAM exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

When DYNA LEVETIRACETAM is used alone:

Adults and children from 16 years of age*:*

The recommended starting dose is 250 mg twice daily which should be increased to an initial dose of 500 mg twice daily after two weeks. The dose can 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.

When DYNA LEVETIRACETAM is taken in combination with other anti- epileptic medicines:

Adults and children older than 12 years of age*:*

The recommended dose is 500 mg twice daily. Depending upon the response and tolerance the daily dose can be increased up to 1 500 mg twice daily. The maximum daily dose is 3 000 mg.

Your doctor may occasionally change your dose to make sure you get the best results from this medicine.

Children:

Children 12 to 17 years of age weighing less than 50 Kg*:*

The recommended dose is 10 mg/kg twice daily.

Depending upon response and tolerability the dose can be increased up to 30 mg/kg twice daily.

DYNA LEVETIRACETAM should not be given to children under the age of 12 years.

Your doctor will tell you how long your treatment with DYNA LEVETIRACETAM will last. Do not stop treatment early because this could increase your seizures. If you have the impression that the effect of DYNA LEVETIRACETAM is too strong or too weak, tell your doctor or pharmacist.

If you take more DYNA LEVETIRACETAM than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- Sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

If you forget to take DYNA LEVETIRACETAM

If you forget to take DYNA LEVETIRACETAM, take as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DYNA LEVETIRACETAM

It is important that you continue the course of treatment. Do not stop treatment early because your seizures can increase. Do not stop taking DYNA LEVETIRACETAM unless your doctor tells you to do so.

4. Possible side effects

DYNA LEVETIRACETAM can have side effects.

Not all side effects reported for DYNA LEVETIRACETAM are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DYNA LEVETIRACETAM, please consult your health care provider for advice.

If any of the following happens, stop using DYNA LEVETIRACETAM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching.

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

- 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
- psychological problems, mood or mental changes, agitation, lack of interest in life, depersonalisation, personality problems, excessively emotional, suicide, suicide attempt,

suicidal ideas, abnormal behaviour, hallucination, anger, state of confusion, panic attack, mood swings, abnormal thinking

- Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters) or any other blisters with a dark ring around the edge or a severe rash with skin peeling
- symptoms such as 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.

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:

- loss of appetite, anorexia
- irritability, anxiety, depression, hostility, problem getting to

sleep, nervousness, aggression

- dizziness (sensation of spinning), headache, sleeping problems, convulsions, balance disorder, involuntary trembling, lack of energy or enthusiasm
- double vision, blurred vision
- vertigo (sensation of rotation)
- diarrhoea, indigestion, nausea, vomiting, abdominal pain
- runny nose, inflammation of nasal passages, sore throat, cough, common cold
- skin rash
- muscle pain, muscle weakness, loss of full control of bodily movement
- unusual weakness or tiredness.

Less frequent side effects:

- infection
- decreased number of red blood cells and/or white blood cells

and /or platelets

- weight loss, weight gain, decreased blood sodium concentration
- destruction of striated muscle cells, muscle tissue damage
- inflammation of the liver, liver failure, abnormal liver test results
- burning and pricking sensation (pins and needles), memory loss, memory impairment, disturbance in attention, abnormal involuntary body movements, impairment of voluntary movement, increased muscular movement
- inflammation of the sinuses (sinusitus)
- eczema, itching, hair loss
- Injury.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug 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 DYNA LEVETIRACETAM.

5. How to store DYNA LEVETIRACETAM

Store all medicines out of reach of children.

Store at or below 30 °C. Keep blisters in carton until required for use.

Do not use after the expiry date stated 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 DYNA LEVETIRACETAM contains

The active substance in each DYNA LEVETIRACETAM 250 mg tablet contains 250 mg levetiracetam.

The active substance in each DYNA LEVETIRACETAM 500 mg tablet contains 500 mg levetiracetam.

The active substance in each DYNA LEVETIRACETAM 750 mg tablet contains 750 mg levetiracetam.

The other ingredients are:
Tablet cores:

Croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, povidone, silica colloidal, talc.

Tablet coating:

Opadry blue AMB 84F80803: (FD & C blue #2/Indigo carmine aluminium lake)

Opadry pink AMB 84F 84674: (FC & C yellow #6 Sunset yellow FCF aluminium lake, iron oxide red, iron oxide yellow)

Opadry white AMB 84F58775

Opadry yellow AMB 84F82508: (Iron oxide yellow)

Excipients common to Opadry variants:

Macrogol 3350, macrogol 6000, polyvinyl alcohol (part hydrolysed), talc, titanium dioxide.

What DYNA LEVETIRACETAM looks like and contents of the pack

DYNA LEVETIRACETAM 250 mg:

Blue, oblong-shaped, biconvex film coated tablets debossed with “250” on one side and a score line on the other side.

DYNA LEVETIRACETAM 500 mg:

Yellow, oblong-shaped, biconvex film coated tablets debossed with “500” on one side and a score line on the other side.

DYNA LEVETIRACETAM 750 mg:

Peach coloured, oblong-shaped, biconvex film coated tablets debossed with “750” on one side and a score line on the other side.

DYNA LEVETIRACETAM tablets are available clear PVC/ Aluminium blister strips containing 10 tablets. Six (6 x 10) or three (3 x 10) blister strips are packed in an outer cardboard box.

Holder of Certificate of Registration

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NAMIBIA:

DYNA LEVETIRACETAM 250 mg: NAM NS2 13/2.5/0178

DYNA LEVETIRACETAM 500 mg: NAM NS2 13/2.5/0179

DYNA LEVETIRACETAM 750 mg: NAM NS2 13/2.5/0180