Approved Patient Information Leaflet for Levetiracetam Unicorn 250 & 750

SCHEDULING STATUS

Schedule 3

PROPRIETARY NAMES AND DOSAGE FORM

LEVETIRACETAM UNICORN 250 film coated tablets

LEVETIRACETAM UNICORN 750 film coated tablets

Read all of this leaflet carefully before you start taking LEVETIRACETAM UNICORN tablets.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, please ask your doctor or your pharmacist.
- **LEVETIRACETAM UNICORN** 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.

1. WHAT LEVETIRACETAM UNICORN CONTAINS

The active substance is levetiracetam.

Each **LEVETIRACETAM UNICORN 250** tablet contains 250 mg levetiracetam.

Each **LEVETIRACETAM UNICORN 750** tablet contains 750 mg levetiracetam.

The other ingredients (for LEVETIRACETAM UNICORN 250 and LEVETIRACETAM UNICORN 750) are:

Croscarmellose sodium, magnesium stearate, polyethylene glycol, povidone, and silica colloidal anhydrous.

LEVETIRACETAM UNICORN 250 contains Opadry Blue (containing FD&C blue No. 2, macrogol, polyvinyl alcohol, talc, and titanium dioxide).

LEVETIRACETAM UNICORN 750 contains Opadry Orange (containing FD&C yellow No. 6, iron oxide red, macrogol, polyvinyl alcohol, talc and titanium dioxide).

2. WHAT LEVETIRACETAM UNICORN IS USED FOR

LEVETIRACETAM UNICORN is an antiepileptic medicine (a medicine used to treat seizures in epilepsy) used in adults and children over 16 years of age.

3. BEFORE YOU USE LEVETIRACETAM UNICORN

Do not take LEVETIRACETAM UNICORN:

- If you are allergic (hypersensitive) to levetiracetam or to any of the other ingredients of **LEVETIRACETAM UNICORN** (see **WHAT LEVETIRACETAM UNICORN CONTAINS**).
- If you are pregnant, suspect that you are pregnant or breastfeeding your baby (see **Pregnancy and breastfeeding**).

Take special care with LEVETIRACETAM UNICORN:

- Do not stop taking **LEVETIRACETAM UNICORN** without first talking to your doctor, even if you feel better. If you stop taking **LEVETIRACETAM UNICORN** suddenly, you may have increased seizures. Tell your doctor if you have new or worsening seizures.
- If you have a kidney disease. You may require a dose adjustment.
- If you have a liver disease. Your doctor will need to assess your kidney function in order to decide on an appropriate dose for you.

Taking LEVETIRACETAM UNICORN with food or drink:

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

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **LEVETIRACETAM UNICORN**.

DO NOT use **LEVETIRACETAM UNICORN** if you are pregnant or suspect that you are pregnant. Contact you doctor immediately.

DO NOT use **LEVETIRACETAM UNICORN** if you are breastfeeding your baby.

Driving and using machinery:

LEVETIRACETAM UNICORN may impair your ability to drive and use machinery. Do not drive, operate machinery, or do anything else that could be dangerous until you know how **LEVETIRACETAM UNICORN** affects you. This effect is more likely to occur when you start treatment or after an increase in your dose.

Using other medicines with LEVETIRACETAM UNICORN:

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

4. HOW TO TAKE LEVETIRACETAM UNICORN

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

Always take **LEVETIRACETAM UNICORN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Do not take **LEVETIRACETAM UNICORN** in larger amounts, or take it for longer than recommended by your doctor. Follow the instructions on your prescription label.

Your doctor may occasionally change your dose to make sure you get the best results from **LEVETIRACETAM UNICORN**.

The usual dose is between 1 000 mg and 3 000 mg each day.

Do not crush, chew or break a **LEVETIRACETAM UNICORN** tablet. Swallow the tablet whole.

It is important to take **LEVETIRACETAM UNICORN** regularly to get the most benefit. Get your prescription refilled before you run out of medicine completely.

Your doctor will tell you how long your treatment with **LEVETIRACETAM UNICORN** will last. Do not stop treatment early because this could increase your seizures.

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

If you take more LEVETIRACETAM UNICORN than you should:

In the event of overdosage, consult your doctor or pharmacist as soon as possible. If neither is available, contact the nearest hospital or poison control centre. Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

If you forget to take your LEVETIRACETAM UNICORN:

If you have missed your dose by only a few hours, take the missed dose 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 extra medicine to make up the missed dose.

Effects when treatment with LEVETIRACETAM UNICORN is stopped:

Do not stop taking **LEVETIRACETAM UNICORN** without first talking to your doctor, even if you feel better. If you stop taking **LEVETIRACETAM UNICORN** suddenly, you may have increased seizures. Tell your doctor if you have new or worsening seizures.

5. POSSIBLE SIDE EFFECTS

LEVETIRACETAM UNICORN can have side effects. Not all side effects reported for **LEVETIRACETAM UNICORN** are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking **LEVETIRACETAM UNICORN**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **LEVETIRACETAM UNICORN** 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.
- Fainting.

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

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

Frequent:

- Seizures (fits).

Less frequent:

- Infection (with symptoms such as fever or sore throat).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent:

- Loss of appetite, or an increase in weight.
- Mood changes, feeling irritable, panic attacks, anger or aggression, nervousness.
- Personality disorders (behaviour problems), thinking abnormally (slow thinking, unable to concentrate), trouble sleeping.
- Loss of memory, forgetfulness, loss of concentration.
- Abnormal coordination of movements, difficulty in controlling movements, uncontrollable muscle spasms, lack of muscle coordination, which may affect your speech, eye movements and your ability to swallow or to walk.
- Involuntary trembling.
- Double vision, blurred vision.
- Dizziness, headache, sleepiness.
- Unusual weakness or tiredness.
- Flu symptoms, runny nose, sore throat, coughing.
- Sensation of spinning.
- Diarrhoea, heartburn, nausea, vomiting, stomach pain.
- Skin rash, with itching, redness and a burning feeling.

- Hair loss (temporary).
- Accidental injury.

Less frequent:

- Numbness, pins and needles.
- A blocked nose.

Frequency unknown:

- Blood test results showing changes in blood platelets.
- Pancreatitis (inflammation of the pancreas).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF LEVETIRACETAM UNICORN

- Store at or below 25 °C.
- Keep the blister strips in the outer carton 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).

7. PRESENTATION OF LEVETIRACETAM UNICORN

LEVETIRACETAM UNICORN 250: Clear PVC/silver aluminium foil blister strips containing 10 tablets. Six blister strips (6 x 10) are packed in an outer cardboard box.

LEVETIRACETAM UNICORN 750: Clear PVC/silver aluminium foil blister strips containing 10 tablets. Six blister strips (6 x 10) are packed in an outer cardboard box.

8. IDENTIFICATION OF LEVETIRACETAM UNICORN

LEVETIRACETAM UNICORN 250: Blue coloured, oblong shaped, film coated tablets, with a scoreline on one side and debossed with ‘250’ on the other side of the tablet.

LEVETIRACETAM UNICORN 750: Orange coloured, oblong shaped, film coated tablets, with a scoreline on one side and debossed with ‘750’ on the other side of the tablet.

9. REGISTRATION NUMBERS

LEVETIRACETAM UNICORN 250: 46/2.5/0338

LEVETIRACETAM UNICORN 750: 46/2.5/0339

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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