

## PACKAGE LEAFLET: INFORMATION FOR THE USER

**[Levetiracetam] 250 mg film-coated tablets**

**[Levetiracetam] 500 mg film-coated tablets**

**[Levetiracetam] 750 film-coated tablets**

**[Levetiracetam] 1000 mg film-coated tablets**

Levetiracetam

### **Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### **In this leaflet:**

1. What [Levetiracetam] is and what it is used for
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## **1. WHAT [LEVETIRACETAM] IS AND WHAT IT IS USED FOR**

[Levetiracetam] film-coated tablets are an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

[Levetiracetam] is used:

- on its own in patients from 16 years of age with newly diagnosed epilepsy, to treat partial onset seizures with or without secondary generalisation.
- as an add-on to other antiepileptic medicines to treat:
  - partial onset seizures with or without generalization in patients from one month of age
  - myoclonic seizures in patients from 12 years of age with juvenile myoclonic epilepsy.
  - primary generalised tonic-clonic seizures in patients from 12 years of age with idiopathic generalized epilepsy

## **2. BEFORE YOU TAKE [LEVETIRACETAM]**

### **Do not take [Levetiracetam]**

- if you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of [Levetiracetam].

### **Take special care with [Levetiracetam]**

- if you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- If you notice any slow down in the growth or unexpected puberty development of your child, please contact your doctor.
- If you notice an increase in seizure severity (e.g. increased number), please contact your doctor.
- A small number of people being treated with anti-epileptics such as Levetiracetam, have

had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal thoughts, please contact your doctor.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

### **Taking Levetiracetam with food and drink**

You may take [Levetiracetam] with or without food. As a safety precaution, do not take [Levetiracetam] with alcohol.

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or if you think you may be pregnant, please inform your doctor.

[Levetiracetam] should not be used during pregnancy unless clearly necessary. The potential risk to your unborn child is unknown. Levetiracetam has shown unwanted reproductive effects in animal studies at dose levels higher than you would need to control your seizures.

Breast-feeding is not recommended during treatment.

### **Driving and using machines**

[Levetiracetam] may impair your ability to drive or operate any tools or machinery, as [Levetiracetam] may make you feel sleepy. This is more likely at the beginning of treatment or after an increase in the dose.

You should not drive or use machines until it is established that your ability to perform such activities is not affected.

### **Important information about some of the ingredients of [Levetiracetam]**

[Levetiracetam] 250mg and 750 mg contains Sunset Yellow FCF (E110). Sunset Yellow FCF (E110) colouring agent may cause allergic reactions.

## **3. HOW TO TAKE [LEVETIRACETAM]**

Always take [Levetiracetam] exactly as your doctor has told you. You should check with your doctor if you are not sure.

[Levetiracetam] 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 following your doctor's instructions.

### ***Monotherapy***

#### **Dose in adults and adolescents (from 16 years of age)**

General dose: between 1000 mg (4 tablets) and 3,000 mg (12 tablets) each day.

500mg:

General dose: between 1000 mg (2 tablets) and 3,000 mg (6 tablets) each day.

750mg, 1000mg:

General dose: between 1000 mg and 3,000 mg each day.

When you will first start taking [Levetiracetam], your doctor will prescribe you a **lower dose** during 2 weeks before giving you the lowest general dose.

*Example: if your daily dose is 1000 mg, you must take 2 tablets in the morning and 2 tablets in the evening.*

500mg:

*Example: if your daily dose is 2,000 mg, you must take 2 tablets in the morning and 2 tablets in the evening.*

750mg:

*Example: if your daily dose is 3,000 mg, you must take 2 tablets in the morning and 2 tablets in the evening.*

1000mg:

*Example: if your daily dose is 2,000 mg, you must take 1 tablet in the morning and 1 tablet in the evening.*

### **Add-on therapy**

#### **Dose in adults and adolescents (12 to 17 years) weighing 50 kg or more**

General dose: between 1,000 mg (4 tablets) and 3,000 mg (12 tablets) each day.

*Example: if your daily dose is 1,000 mg, you must take 2 tablets in the morning and 2 tablets in the evening.*

500mg:

General dose: between 1,000 mg (2 tablets) and 3,000 mg (6 tablets) each day.

*Example: if your daily dose is 1,000 mg, you must take one tablet in the morning and one tablet in the evening.*

750mg:

General dose: between 1,000 mg and 3,000 mg each day.

*Example: if your daily dose is 1,500 mg, you must take one tablet in the morning and one tablet in the evening.*

1000mg:

General dose: between 1,000 mg and 3,000 mg each day.

*Example: if your daily dose is 2,000 mg, you must take one tablet in the morning and one tablet in the evening.*

#### **Dose in infants (6 to 23 months), children (2 to 11 years) and adolescents (12 to 17 years) weighing less than 50 kg**

Your doctor will prescribe the most appropriate pharmaceutical form of Levetiracetam according to the age, weight and dose.

Levetiracetam 100 mg/ml oral solution is a presentation more appropriate to infants and children under the age of 6 years.

General dose: between 20 mg per kg bodyweight and 60 mg per kg bodyweight each day.

*Example: a general dose of 20 mg per kg bodyweight each day, you must give your 25kg child 1 tablet in the morning and 1 tablet in the evening.*

#### **Dose in infants (1 month to less than 6 months)**

Levetiracetam 100mg/ml oral solution is a presentation more appropriate to infants.

### **Method of administration**

Swallow [Levetiracetam] tablets with a sufficient quantity of liquid (*e.g.* a glass of water).

### **Duration of treatment**

- [Levetiracetam] is used as a chronic treatment. You should continue Levetiracetam treatment for as long as your doctor has told you.
- Do not stop your treatment without your doctor's advice as this could increase your seizures.  
Should your doctor decide to stop your [Levetiracetam] treatment, he/she will instruct you about the gradual withdrawal of [Levetiracetam].

### **If you take more [Levetiracetam] than you should**

The possible side effects of an overdose of [Levetiracetam] are sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

Contact your doctor if you took more tablets than you should. Your doctor will establish the best possible treatment of overdose.

### **If you forget to take [Levetiracetam]**

Contact your doctor if you have missed one or more doses.  
Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking [Levetiracetam]**

If stopping treatment, as with other antiepileptic medicines, [Levetiracetam] should be discontinued gradually to avoid an increase of seizures.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, [Levetiracetam] can cause side effects, although not everybody gets them. Tell your doctor if you have any of the following and they worry you.

Some of the side effects like sleepiness, tiredness and dizziness may be more common at the beginning of the treatment or at dose increase. These effects should however decrease over time.

##### **Very common** (affects more than 1 user in 10):

- somnolence (sleepiness);
- asthenia/fatigue (tiredness).

##### **Common** (affects 1 to 10 users in 100):

- infection, nasopharyngitis;
- decreased number of blood platelets;
- anorexia (loss of appetite), weight increase;
- agitation, depression, emotional instability/mood swings, hostility or aggression, insomnia, nervousness or irritability, personality disorders (behavioural problems), thinking abnormal, (slow thinking, unable to concentrate);
- dizziness (sensation of unsteadiness), convulsion, headache, hyperkinesia (hyperactivity), ataxia, (impaired coordinated movements), tremor (involuntary trembling), amnesia (loss of memory), balance disorder (equilibrium disorder), disturbance in attention (loss of concentration), memory impairment (forgetfulness);
- diplopia (double vision), vision blurred;
- vertigo (sensation of rotation);
- cough (increase of pre-existing cough);
- abdominal pain, nausea, dyspepsia (indigestion), diarrhoea, vomiting;
- rash, eczema, pruritus;
- myalgia (muscle pain);
- accidental injury.

##### **Not known** (frequency cannot be estimated from the available data):

- decreased number of red blood cells, and/or white blood cells;
- weight loss;
- abnormal behaviour, anger, anxiety, confusion, hallucination, mental disorder, suicide, suicide attempt and suicidal ideation;
- paraesthesia (tingling), difficulty in controlling movements, uncontrollable muscle spasms affecting the head, torso and limbs;
- pancreatitis, hepatic failure, hepatitis, liver function test abnormal;
- hair loss, blistering of the skin, mouth, eyes and genital area, skin eruption.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE [LEVETIRACETAM]

Keep out of the reach and sight of children.

Do not use after the expiry date stated on the carton box and blister after EXP.  
The expiry date refers to the last day of the month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What [Levetiracetam] contains

- The active substance is called levetiracetam.

[Levetiracetam] 250mg film coated tablet contains 250 mg of levetiracetam.

[Levetiracetam] 500mg film coated tablet contains 500 mg of levetiracetam.

[Levetiracetam] 750mg film coated tablet contains 750 mg of levetiracetam.

[Levetiracetam] 1000mg film coated tablet contains 1000 mg of levetiracetam.

The other ingredients are:

[Levetiracetam] 250mg film coated tablet

Tablet core: Calcium hydrogen phosphate dihydrate, cellulose microcrystalline, crospovidone, hydroxypropylcellulose.

Tablet-coating: Opadry 02H20569 (hypromellose, titanium dioxide, talc, propylenene glycol, indigo carmine aluminium lake (E132), sunset yellow FCF aluminium lake (E110), Quinoline yellow aluminium lake (E104).

[Levetiracetam] 500mg film coated tablet

Tablet core: Calcium hydrogen phosphate dihydrate, cellulose microcrystalline, crospovidone, hydroxypropylcellulose.

Tablet-coating: Opadry 20J22730 (hypromellose, titanium dioxide, hydroxypropylcellulose, propylenene glycol, sorbitan monooleate, sorbic acid FCC, vanillin, quinoline yellow aluminium lake (E104)

[Levetiracetam] 750mg film coated tablet

Tablet core: Calcium hydrogen phosphate dihydrate, cellulose microcrystalline, crospovidone, hydroxypropylcellulose.

Tablet-coating: Opadry OY-S-33016 (hypromellose, titanium dioxide (E171), macrogol 4000, Iron oxide red (E172), indigocarmine aluminum lake (E132), sunset yellow FCF aluminum lake (E110),

[Levetiracetam] 1000mg film coated tablet

Tablet core: Calcium hydrogen phosphate dihydrate, cellulose microcrystalline, crospovidone, hydroxypropylcellulose.

Tablet-coating: Opadry OY-LS-28908 (titanium dioxide (E171), lactose monohydrate, hypromellose, macrogol 4000,

[Levetiracetam] film-coated tablets are packed in white opaque PVC/PE/PVDC-Aluminum foil blister in cardboard boxes.

### What [Levetiracetam] looks like and contents of the pack

The 250mg film-coated tablets are blue, oblong, biconvex film-coated tablets.

The 500mg film-coated tablets are yellow, oblong, biconvex film-coated tablets.

The 750mg film-coated tablets are pink, oblong, biconvex film-coated tablets.

The 1000mg film-coated tablets are white, oblong, biconvex film-coated tablets.

The cardboard boxes contain 10, 20, 30, 50, 60, 80, 100, 120 and 200 film-coated tablets.

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer**

<[To be completed nationally]>