**Package leaflet: Information for the patient**

Levetiracetam Cipla 1000 mg film-coated tablets
Levetiracetam

**Read all of this leaflet carefully before you or your child start taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctoror pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**



## 1. What Levetiracetam Cipla is and what it is used for

Levetiracetam is are an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Levetiracetam Cipla is used:

- on its own in adults and adolescents from 16 years of age with newly diagnosed epilepsy, to treat a certain form of epilepsy. Epilepsy is a condition where the patients have repeated fits (seizures). Levetiracetam Cipla is used for the epilepsy form in which the fits initially affect only one side of the brain, but could thereafter extend to larger areas on both sides of the brain (partial onset seizure with or without secondary generalisation). Levetiracetam Cipla has been given to you by your doctor to reduce the number of fits.

- As an add-on to other antiepileptic medicines to treat:

    - partial onset seizures with or without generalisation in adults, adolescents, children and infants from one month of age

    - 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 12 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

## 2. What you need to know before you take Levetiracetam Cipla

**Do not take Levetiracetam Cipla**

- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine (listed in Section 6)

**Warnings and precautions**

Talk to your doctor before taking Levetiracetam Cipla

- 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.

- A small number of people being treated with anti-epileptics such as Levetiracetam Cipla have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

**Children and adolescents**
Levetiracetam Cipla is not indicated in children and adolescents below 16 years on its own (monotherapy)

**Other medicines and Levetiracetam Cipla**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking Levetiracetam Cipla as this may results in a loss of its effect.

**Pregnancy and breast-feeding**

If you are pregnant or breast-feeding think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Levetiracetam Cipla should not be used during pregnancy unless clearly necessary. The potential risk to your unborn child is unknown.

Levetiracetam Cipla 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 Cipla may impair your ability to drive or operate any tools or machinery, as it 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.

## 3. How to take Levetiracetam Cipla

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Take the number of tablets following your doctor's instructions.

Levetiracetam Cipla must be taken twice a day, once in the morning and once in the evening, at about the same time each day.

**Monotherapy**

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

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

When you will first start taking Levetiracetam Cipla, your doctor will prescribe you a lower dose (500 mg each day) during 2 weeks before giving you the lowest general dose of 1000 mg.

Example: if your daily dose is 1000 mg, your reduced starting dose is 2 tablets of 250 mg in the morning and 2 tablets of 250 mg in the evening.

**Add-on therapy**

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

General dose: between 1000 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 (1 month 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.

A levetiracetam 100 mg/ml oral solution is a formulation more appropriate to infants and children under the age of 6 years and to children and adolescent (from 6 to 17 years) weighing less than 50kg and when tablets don't allow accurate dosage.

**Method of administration:**

Swallow Levetiracetam Cipla tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take Levetiracetam Cipla with or without food.

**Duration of treatment:**

- Levetiracetam Cipla is used as a chronic treatment. You should continue Levetiracetam Cipla 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.

**If you take more Levetiracetam Cipla than you should:**

The possible side effects of an overdose of Levetiracetam Cipla 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 Cipla:**

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 Cipla:**

If stopping treatment, Levetiracetam Cipla should be discontinued gradually to avoid an increase of seizures. Should your doctor decide to stop your Levetiracetam Cipla treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam Cipla.

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

## 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most frequently reported side effects are nasopharyngitis, somnolence (sleepiness), headache, fatigue and dizziness. At the beginning of the treatment or at dose increaseside effects like sleepiness, tiredness and dizziness may be more common. These effects should however decrease over time.

**Very common**: may affect more than 1 user in 10 people
- nasopharyngitis;
- Somnolence (sleepiness), headache.

**Common**: may affect 1 to 10 users in 100 people
- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy (lack of energy and enthusiasm), tremor (involuntary trembling);
- vertigo (sensation of rotation);
- cough;
- abdominal pain, diarrhoea, dyspepsia (indigestion), vomiting,
- nausea;
- rash;
- asthenia/fatigue (tiredness).

**Uncommon**: may affect 1 to 10 users in 1000 people

- decreased number of blood platelets, decreased number of white blood cells;
- weight decrease, weight increase;
- suicide attempt and suicidal ideation, mental disorder, abnormal behaviour, hallucination, anger, confusion, panic attack, emotional instability/mood swings, agitation;
- amnesia (loss of memory), memory impairment (forgetfulness), abnormal coordination/ataxia (impaired coordinated movements), paraesthesia (tingling), disturbance in attention (loss of concentration);
- diplopia (double vision), vision blurred;
- elevated/abnormal values in a liver function test;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury

**Rare**: may affect 1 to 10 users in 10,000 people
- infection;
- decreased number of all blood cell types;
- severe allergic reactions (DRESS, anaphylactic reaction [severe and important allergic reaction], Quincke's oedema [swelling of the face, lips, tongue and throat]);
- decreased blood sodium concentration;
- severe reduction in number of white blood cells which makes infections more likely;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- liver failure, hepatitis;
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme), a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens–Johnson syndrome), and a more severe form causing skin peeling in more than 30% of the body surface (toxic epidermal necrolysis).

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can report side effects directly (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.hpra.ie
e-mail: medsafety@hpra.ie

## 5. How to store Levetiracetam Cipla

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

### What Levetiracetam Cipla contains

The active substance is called levetiracetam. Each tablet contains 1000 mg of levetiracetam.
The other ingredients are:

Tablet core: Croscarmellose sodium, Maize starch, Povidone K- 30, Silica colloidal anhydrous, Magnesium stearate.

Film-coating: Hypromellose 15cP (E464), Titanium dioxide (E171) and Macrogol 6000.

### What Levetiracetam Cipla looks like and contents of the pack

Levetiracetam Cipla 1000 mg film-coated tablets are white, capsule shaped, biconvex, length: 20.9 mm to 21.3 mm, width: 8.9 mm to 9.3 mm and thickness: 7.3 mm to 7.9 mm, film-coated tablets plain on both sides

Aluminium/PVC/PE/PVDC blisters placed into cardboard boxes containing 10, 20, 30, 50, 60, 100, 120 and 200 film-coated tablets.

Not all pack sizes may be marketed.

### Marketing Authorisation Holder and Manufacturer

**Marketing Authorisation Holder**
Cipla (EU) Limited, Hillbrow House, Hillbrow Road, Esher, Surrey, KT10 9NW, United Kingdom

**Manufacturer**
Cipla (EU) Limited, 20 Balderton Street, London W1K 6TL,United Kingdom
S&D Pharma CZ, spol. s r.o., Theodor 28, 273 08 Pchery (Pharmos a.s. facility), Czech Republic
Cipla Europe NV, Uitbreidingstraat 80, 2600 Antwerp, Belgium

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