

Package Leaflet: Information for the patient

Levetiracetam Clonmel 250 mg film-coated tablets
Levetiracetam Clonmel 500 mg film-coated tablets
Levetiracetam Clonmel 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 doctor or 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levetiracetam Clonmel is and what it is used for
2. What you need to know before you take Levetiracetam Clonmel
3. How to take Levetiracetam Clonmel
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1. What Levetiracetam Clonmel is and what it is used for

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

Levetiracetam Clonmel 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 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 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 Clonmel

Do not take Levetiracetam Clonmel

- 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 Clonmel

- 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 Clonmel have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or

suicidal ideation, please contact your doctor.

- 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.

Tell your doctor or pharmacist if any of the following side effects gets serious or last longer than a few days:

- 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.
- Aggravation of epilepsy
- Your seizures may rarely become worse or happen more often, mainly during the first month after the start of the treatment or increase of the dose. If you experience any of these new symptoms while taking Levetiracetam Clonmel, see a doctor as soon as possible.

Children and adolescents

Levetiracetam Clonmel is not indicated in children and adolescents below 16 years on its own (monotherapy).

Other medicines and Levetiracetam Clonmel

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

Do not take macrogol (a medicine used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a reduction 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 can be used during pregnancy, only if after careful assessment it is considered necessary by your doctor.

You should not stop your treatment without discussing this with your doctor.

A risk of birth defects for your unborn child cannot be completely excluded.

Breast-feeding is not recommended during treatment.

Driving and using machines

Levetiracetam Clonmel 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 Clonmel

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

Levetiracetam Clonmel is not available in all pharmaceutical forms described. For dosing recommendations not achievable with Levetiracetam Clonmel, other medicines containing levetiracetam should be used.

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

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

Adjunctive therapy and monotherapy (from 16 years of age)

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

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

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

Example: if your daily dose is intended to be 1,000 mg, your reduced starting dose is 1 tablet of

250 mg in the morning and 1 tablet of 250 mg in the evening, and the dose will be gradually incremented to reach 1,000 mg daily after 2 weeks.

- **Adolescents (12 to 17 years) weighing 50 kg or less:**

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

- **Dose in infants (1 month to 23 months) and children (2 to 11 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 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 50 kg and when tablets don't allow accurate dosage.

Method of administration

Levetiracetam Clonmel is for oral use.

Swallow the tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take Levetiracetam Clonmel with or without food. After oral administration the bitter taste of levetiracetam may be experienced.

Duration of treatment

- Levetiracetam Clonmel is used as a chronic treatment. You should continue Levetiracetam Clonmel 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 Clonmel than you should

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

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

If you forget to take Levetiracetam Clonmel

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

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

If you stop taking Levetiracetam Clonmel

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

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.

Tell your doctor immediately, or go to your nearest emergency department, if you experience:

- weakness, feel light-headed or dizzy or have difficulty breathing, as these may be signs of a serious allergic (anaphylactic) reaction
- swelling of the face, lips, tongue and throat (Quincke's oedema)
- 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 cell (eosinophilia) and enlarged lymph nodes (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS])
- 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

- 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) (*erythema multiforme*)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (*Stevens-Johnson syndrome*)
- a more severe form of rash causing skin peeling in more than 30 % of the body surface (*toxic epidermal necrolysis*)
- 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. These could be symptoms of an encephalopathy

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

Very common (may affect more than 1 in 10 people):

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common (may affect up to 1 in 10 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 up to 1 in 100 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 up to 1 in 1,000 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;
- suicide, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- delirium;
- encephalopathy (see sub-section "Tell your doctor immediately" for a detailed description of

symptoms);

- seizures may become worse or happen more often;
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- change of the heart rhythm (Electrocardiogram);
- pancreatitis;
- liver failure, hepatitis;
- sudden decrease in kidney function
- 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*).
- rhabdomyolysis (breakdown of muscle tissue) and associated blood creatine phosphokinase increase. Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients;
- limp or difficulty walking.

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 also report side effects directly via the national reporting system:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levetiracetam Clonmel

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 and blister after EXP. The expiry date refers to the last day of that 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 Clonmel contains

The active substance is levetiracetam.

Each film-coated tablet of Levetiracetam Clonmel 250 mg contains 250 mg levetiracetam.

Each film-coated tablet of Levetiracetam Clonmel 500 mg contains 500 mg levetiracetam.

Each film-coated tablet of Levetiracetam Clonmel 1000 mg contains 1000 mg levetiracetam.

The other ingredients are:

Tablet core:

Crospovidone (Type B), Povidone K30, Silica colloidal anhydrous, Magnesium stearate.

Film-coating:

250mg:

Hypromellose, Macrogol 400, Titanium Dioxide (E171), Talc, Indigo Carmine, Aluminium Lake (E132)

500mg:

Hypromellose, Macrogol 400, Titanium Dioxide (E171), Talc, Iron Oxide Yellow (E172)

1000mg:

Hypromellose, Macrogol 400, Titanium Dioxide (E171), Talc.

What Levetiracetam Clonmel looks like and contents of the pack

250 mg: Blue, oval shaped film-coated tablets with a score line on one side, with dimensions 12.9 x 6.1 mm. The tablet can be divided into equal doses.

500 mg: Yellow, oval shaped film-coated tablets with a score line on one side with dimensions 16.5 x 7.7 mm. The tablet can be divided into equal doses.

1000 mg: White, oval shaped film-coated tablets with a score line on one side, with dimensions 19.2 x 10.2 mm. The tablet can be divided into equal doses.

The film-coated tablets are packed in aluminium/PVC-PE-PVDC blisters and placed into cardboard boxes containing:

Levetiracetam Clonmel 250 mg is packed in cardboard boxes containing 20, 30, 50, 60, 100 and 200 film-coated tablets.

Levetiracetam Clonmel 500 mg is packed in cardboard boxes containing 10, 20, 30, 50, 60, 100, 120 and 200 film-coated tablets.

Levetiracetam Clonmel 1000 mg is packed in cardboard boxes containing 10, 20, 30, 50, 60, 100 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing authorisation holder

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

Manufacturer

Rontis Hellas S.A., Medical and Pharmaceutical Products P.O. Box 3012 Larisa Industrial Area, Larisa, 41004, Greece

PharOS MT Ltd, HF 62X, Hal Far Industrial Estate, Birzebbugia, BBG 3000, Malta

STADA Arzneimittel AG, Stadastrasse 2-18, 61118 Bad Vilbel, Germany

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

This medicinal product is authorised in the Member States of the EEA under the following names:

Germany:	Levetiracetam STADA 250, 500, 750, 1000 mg Filmtabletten
Austria :	Levetiracetam STADA 250, 500, 1000 mg Filmtabletten
Czech Republic:	Levetiracetam STADA Arzneimittel AG
Spain:	Levetiracetam Stadafarma 500, 1000 mg comprimidos recubiertos con película EFG
France:	Levetiracetam EG LABO 250, 500, 1000 mg, comprimé pelliculé
Hungary:	Levetiracetam STADA Arzneimittel 500 mg filmtabletta
Ireland:	Levetiracetam Clonmel 250, 500, 1000 mg film-coated tablets
Iceland:	Levetiracetam STADA Arzneimittel 250, 500, 750, 1000 mg filmuhúðaðar töflur
Netherlands:	Levetiracetam CF 250, 500, 1000 mg filmomhulde tabletten
Portugal:	Levetiracetam Ciclum Farma
Slovak Republic:	Levetiracetam STADA Arzneimittel 250, 500, 1000 mg filmom obalené tablety

This leaflet was last revised in June 2021.