

Package Leaflet: Information for the patient

Levetiracetam Torrent 250mg film-coated tablets  
Levetiracetam Torrent 500mg film-coated tablets  
Levetiracetam Torrent 750mg film-coated tablets  
Levetiracetam Torrent 1000mg film-coated tablets



Levetiracetam

Read all of this leaflet carefully before you 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 Torrent is and what it is used for
2. What you need to know before you take Levetiracetam Torrent
3. How to take Levetiracetam Torrent
4. Possible side effects
5. How to store Levetiracetam Torrent
6. Contents of the pack and other information

1. What LEVETIRACETAM TORRENT is and what it is used for

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

- Levetiracetam is used: on its own in adults and adolescents 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 generalisation in adults, adolescents, children and infants from one month of age
  - myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
  - primary generalised tonic-clonic seizures in adults and adolescents from 12 years of age with idiopathic generalized epilepsy.

2. What you need to know before you take LEVETIRACETAM TORRENT

Do not take Levetiracetam Torrent:

- If you are allergic to levetiracetam or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking 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 ideation, please contact your doctor.

Other medicines and Levetiracetam Torrent:

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

Taking Levetiracetam Torrent with food ,drink and alcohol:

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

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 or pharmacist for advice before taking this medicine. Levetiracetam should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. 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.

Only for Levetiracetam Torrent 750 mg film-coated tablets:  
Levetiracetam Torrent contains Sunset Yellow aluminium lake (E110)

Levetiracetam 750 mg film-coated tablets contain the colouring agent Sunset Yellow aluminium lake (E110) which may cause allergic reactions.

3. How to take LEVETIRACETAM TORRENT

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 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 1,000 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.

Add-on therapy

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

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

Dose in infants (6 to 23 months), in 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 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.

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

For infants presentations with oral solution should be used instead of Levetiracetam film-coated tablets.

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 Torrent 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 Torrent:

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 Torrent:

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 medicine, ask your doctor or pharmacist.

4. Possible side effects

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

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: may affect more than 1 user in 10

- Nasopharyngitis
- somnolence (sleepiness), headache.

Common: may affect 1 to 10 users in 100

- anorexia (loss of appetite);
- depression, hostility or aggression, anxiety, insomnia, nervousness or irritability;
- convulsion, balance disorder (equilibrium disorder), dizziness (sensation of unsteadiness), lethargy, 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

- 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;
- liver function test abnormal;
- hair loss, eczema, pruritus;
- muscle weakness, myalgia (muscle pain);
- injury.

Rare: may affect 1 to 10 users in 10,000

- infection;
- decreased number of all blood cell types
- severe hypersensitivity reactions (DRESS);
- decreased blood sodium concentration;
- 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
- hepatic 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 also report side effects directly via [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LEVETIRACETAM TORRENT

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

Do not use this medicine after the expiry date stated on the carton box 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 Torrent contains:

- The active substance is called levetiracetam.

Levetiracetam Torrent 250 mg film-coated tablets

Each film-coated tablet contains 250 mg of levetiracetam.

Levetiracetam Torrent 500 mg film-coated tablets

Each film-coated tablet contains 500 mg of levetiracetam.

Levetiracetam Torrent 750 mg film-coated tablets

Each film-coated tablet contains 750 mg of levetiracetam.

Levetiracetam Torrent 1000 mg film-coated tablets

Each film-coated tablet contains 1000 mg of levetiracetam.

- The other ingredients are:

Levetiracetam Torrent 250 mg

Tablet core: Maize starch, Sodium starch glycolate (Type A), Silica Colloidal Anhydrous, Povidone (K-30), Talc, Magnesium Stearate  
Film-coating: Hypromellose, Titanium Dioxide (E171), Macrogol 400, Indigo Carmine aluminium lake (E132)

Levetiracetam Torrent 500 mg

Tablet core: Maize starch, Sodium starch glycolate (Type A), Silica Colloidal Anhydrous, Povidone (K-30), Talc, Magnesium Stearate  
Film-coating: Hypromellose, Titanium Dioxide (E171), Macrogol 400, Ferric Oxide Yellow (E172)

Levetiracetam Torrent 750 mg

Tablet core: Maize starch, Sodium starch glycolate (Type A), Silica Colloidal Anhydrous, Povidone (K-30), Talc, Magnesium Stearate  
Film-coating: Hypromellose, Titanium Dioxide (E171), Macrogol 400, Ferric Oxide Red (E 172), Sunset Yellow aluminium lake

Levetiracetam Torrent 1000 mg

Tablet core: Maize starch, Sodium starch glycolate (Type A), Silica Colloidal Anhydrous, Povidone (K-30), Talc, Magnesium Stearate  
Film-coating: Hypromellose, Titanium Dioxide (E171), Macrogol 400

Levetiracetam film-coated tablets are packed in blisters in cardboard boxes.

What Levetiracetam Torrent looks like and contents of the pack

Levetiracetam Torrent 250 mg

The film-coated tablets are blue colored, oval shaped, 12.9 x 6.1 mm, and debossed with break line separating '250' and 'MG' on one side and '1014' on other side. The tablet can be divided into equal halves.

The cardboard boxes contain 28, 30, 50, 60, 100 and 200 film-coated tablets.

Levetiracetam Torrent 500 mg

The film-coated tablets are yellow colored, oval shaped, 16.2 x 7.3 mm, and debossed with breakline separating '500' and 'MG' on one side and '1015' on other side. The tablet can be divided into equal halves.

The cardboard boxes contain 28, 30, 50, 60, 100 and 200 film-coated tablets.

Levetiracetam Torrent 750 mg

The film-coated tablets are orange colored, oval shaped, 18.8 x 8.8. mm, and debossed with breakline separating '750' and 'MG' on one side and '1016' on other side. The tablet can be divided into equal halves.

The cardboard boxes contain 28, 30, 50, 60, 100 and 200 film-coated tablets.

Levetiracetam Torrent 1000 mg

The film-coated tablets are white colored, oval shaped, 20.1 x 9.8 mm, and debossed with breakline separating '1000' and 'MG' on one side and '1017' on other side. The tablet can be divided into equal halves.

The cardboard boxes contain 28, 30, 50, 60, 100 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (UK) Ltd.

Unit 4, Charlwood Court,

County Oak Way

Crawley

West Sussex. RH11 7XA

United Kingdom

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

Germany: Levetiracetam Heumann 250/500/750/1000 mg Filmtabletten

Italy: Levetiracetam Torrent

Lithuania: Levetiracetamas Torrent 250/500/750/1000 mg plėvele dengtos tabletės

Romania: Levetiracetam Torrent 250/500/750/1000 mg comprimate filmate

United Kingdom: Levetiracetam Torrent 250/500/750/1000 mg film-coated tablets

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Colour Black

LOCATION : Indrad	COUNTRY : UK	Supersedes A/W No.:		
SIZE : 180 x 440 mm_Front/Back Side	CODE : 8047494-7803	DATE : 09-04-2014		
REMARK : Folding Length 35 mm				
SUBSTRATE :				
Activities	Department	Name	Signature	Date
Prepared By	Pkg.Dev			
Reviewed By	Pkg.Dev			
Reviewed By	RA			
Approved By	CQA			



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