

# TORLEVA TABLET

Levetiracetam (500mg, 1000mg)

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## What Torleva is used for

Torleva 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 and children from 4 years 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.

## How Torleva works

Torleva is used to control epilepsy. Epilepsy is a condition where you have repeated seizures. There are many different types of seizures, ranging from mild to severe.

This medicine belongs to a group of medicines called anti-epileptics. These medicines are thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

### - When you must not use it

Do not take Torleva if:

- You are allergic (hypersensitive) to levetiracetam or any of the other ingredients.
- Pregnant or trying to get pregnant or think you may be pregnant.
- Breastfeeding.

## Pregnancy and lactation

Do not take Torleva if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take Torleva if you are breast-feeding. Ask your doctor or pharmacist for advice before taking any medicine.

### - Before you start use it

Talk to your doctor before taking Torleva:

- If you suffer from kidney problems, follow your doctor's instructions. He/she may decide if your dose should be adjusted.
- 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.

### - Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are taking:

- Carbamazepine.
- Phenytoin.
- Valproate.
- Lamotrigine.
- Phenobarbital.
- Primidone.
- Gabapentin.

## How to use Torleva

### - How much to use

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

### **Adults (>18 years) and adolescents (12-17years) of >50 kg:**

As adjunctive therapy, the initial therapeutic dose is 500mg twice daily. This dose can be started on the first day of treatment. Depending upon the clinical response and tolerance, the daily dose can be increased up to

1500mg twice daily. Dose changes can be made in 500mg twice daily increments or decrements. The maximum recommended daily dose is 3000mg.

### **Patients with Kidney Impairment:**

The Torleva daily dose must be individualized according to kidney function.

### **Infants and Children (<4 years):**

To date, there are no data to support the use of levetiracetam in patients less than 4 years of age due to insufficient data on safety and efficacy.

### - When to use it

The film-coated tablets must be taken orally, swallowed with liquid and may be taken with or without food. The daily dose is administered in two equally divided doses.

### - How long to use it

Continue taking Torleva for as long as your doctor recommends

### - If you forget to use it

It is important to take your Torleva tablet regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. In that case, just carry on with the next dose as normal. Do not take a double dose to make up for a forgotten dose.

### - If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Signs and symptoms included:

- Somnolence.
- Agitation.
- Aggression.

## While you are using it

### - Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell all the doctors, dentists and pharmacists that are treating you that you are taking Torleva.

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- Tell your doctor immediately if you become pregnant while taking this medication.
- Tell your doctor immediately if you have symptoms of depression or thoughts of harming yourself.

## - Things you must not do

- Do not stop taking your medicine unless your doctor tells you to.
- Do not take any new medicines without consulting your doctor.
- Do not give Torleva to anyone else, even if they have the same symptoms or condition as you.

## - Things to be careful of

### Alcohol Consumption

Do not take Levetiracetam with alcohol.

### Driving and using machines

This medicine may affect your ability to drive or use machines. If the tablets make you feel sick, dizzy or drowsiness or tired do not drive or use machines and contact your doctor immediately.

## **Side effects**

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

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

Tell your doctor if any of the following continue or worry you:

- Asthenia (weakness), headache, infection, pain and flu syndrome, face edema (swelling), neck pain and viral infection.
- Anorexia (eating disorder), diarrhea, vomiting, gastroenteritis (inflammation of the stomach and intestines) and constipation.
- Somnolence (sleepiness), dizziness, depression, nervousness, personality disorder, agitation, reflexes increased and confusion, ataxia (loss of full control of bodily movements), vertigo (sensation of whirling and loss of balance), amnesia (a partial or total loss of memory), anxiety, hostility, paresthesia (pins and needles sensation) and emotional liability.
- Pharyngitis (inflammation of the pharynx, causing a sore throat),

rhinitis (inflammation of the mucous membrane of the nose), asthma, cough increased and sinusitis (inflammation of a nasal sinus).

- Diplopia (double vision), conjunctivitis (inflammation of the conjunctiva of the eye), amblyopia (impaired or dim vision without obvious defect or change in the eye) and ear pain.
- Pruritus (severe itching of the skin), skin discoloration and vesiculobullous rash.
- Albuminuria (condition of having too much protein in the urine) and urine abnormality.

Tell your doctor immediately if you notice any of the following:

- Symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles or feet, may be a sign of sudden decrease of kidney function.
- Signs or symptoms including muscle ache, feeling of weakness and dark urine may indicate the side effect of rhabdomyolysis (breakdown of muscle tissue).
- 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.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Tell your doctor if you get any side effect that bothers you or that does not go away.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) [Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## **Storage and Disposal of Torleva**

### - Storage

- Store below 30°C.

### - Disposal

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.

## **Product Description**

### - What it looks like

#### **TORLEVA 500MG TABLET:**

Yellow colored, oval shaped, film coated tablets debossed with break line separating '500' and 'MG' on one side and '1015' on other side.

#### **TORLEVA 1000MG TABLET:**

White to off white, oval shaped, film coated tablets debossed with breakline separating '1000',and 'MG' on one side and '1017' on other side.

### - Ingredients

Active ingredient:

- Levetiracetam.

Inactive ingredients:

- Starch.
- Sodium Starch Glycolate.
- Colloidal Silicon Dioxide.
- Povidone.
- Talc.
- Magnesium Stearate.
- Hypromellose 2910.
- Titanium Dioxide.
- Polyethylene Glycol 400.
- Ferric Oxide Yellow (Torleva 500mg Tablet Only).

### - MAL number(s):

#### **TORLEVA 500MG TABLET:**

MAL09100256AZ

#### **TORLEVA 1000MG TABLET:**

MAL09100259AZ

## **Manufacturer**

Torrent Pharmaceuticals Limited  
Indrad 382 721, Tal: Kadi,  
City: Indrad, Dist. Mehsana,  
India

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Levetiracetam (500mg, 1000mg)

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## Product Registration Holder

Laboratories Torrent (Malaysia) Sdn.  
Bhd.  
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No. 2 Jalan Kiara Mont Kiara,  
50480 Kuala Lumpur,  
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## Date of revision

02/04/2020

## Serial Number

NPRA(R2/1)200322/398.