

Package leaflet: Information for the patient

Levetiracetam TAD 500 mg 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.

What is in this leaflet:

1. What Levetiracetam TAD is and what it is used for
2. What you need to know before you take Levetiracetam TAD
3. How to take Levetiracetam TAD
4. Possible side effects
5. How to store Levetiracetam TAD
6. Contents of the pack and other information

1. What Levetiracetam TAD is and what it is used for

Levetiracetam TAD 500 mg film-coated tablets are an antiepileptic medicine (a medicine used to treat seizures in epilepsy).

Levetiracetam TAD 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 generalised epilepsy

2. What you need to know before you take Levetiracetam TAD

Do not take Levetiracetam TAD:

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

Warnings and Precautions:

Talk to your doctor before taking Levetiracetam TAD.

- 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 TAD 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 TAD:

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

Levetiracetam TAD with food, drink and alcohol:

You may take Levetiracetam TAD with or without food. As a safety precaution, do not take Levetiracetam TAD 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 TAD should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. Levetiracetam TAD 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 TAD may impair your ability to drive or operate any tools or machinery, as Levetiracetam TAD 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 TAD

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 TAD 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 (2 tablets) and 3,000 mg (6 tablets) each day.

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

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

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.

An 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):

An oral solution is a presentation more appropriate to infants.

Method of administration:

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

Duration of treatment:

- Levetiracetam TAD is used as a chronic treatment. You should continue Levetiracetam TAD 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 TAD treatment, he/she will instruct you about the gradual withdrawal of Levetiracetam TAD.

If you take more Levetiracetam TAD than you should:

The possible side effects of an overdose of Levetiracetam TAD 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 TAD:

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 TAD:

If stopping treatment, as with other antiepileptic medicines, Levetiracetam TAD 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;
- 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*).

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

5. How to store Levetiracetam TAD

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 the month.

Store below 25°C.

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 TAD contains

The active substance is called levetiracetam. Each film-coated tablet contains 500 mg of levetiracetam.

The other ingredients are:

Tablet core: Maize starch, colloidal anhydrous silica, copovidone, crospovidone, magnesium stearate

Film-coating: Hypromellose, talc, titanium dioxide (E 171), macrogol, yellow iron oxide (E 172)

What Levetiracetam TAD looks like and contents of the pack

The film-coated tablets are pale yellow, oblong with one break-mark on both sides, 17.2 x 8.2 x 6.4 mm. The tablet can be divided into equal halves.

The cardboard boxes contain 10, 14, 15, 20, 30, 50, 60, 100, 120, 200 film-coated tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

<to be completed nationally>

Manufacturer

TAD Pharma GmbH
Heinz-Lohmann-Straße 5
27472 Cuxhaven
Germany

Krka, d.d., Novo mesto
Šmarješka cesta 6
8501 Novo mesto
Slovenia

This medicinal product is authorised in the Member States of the EEA under the following names:
<To be completed nationally>

This leaflet was last revised in 2014-01-14