

Package leaflet: information for the patient

**Levetiracetam Tiefenbacher 250 mg film-coated tablets.
Levetiracetam Tiefenbacher 500 mg film-coated tablets.
Levetiracetam Tiefenbacher 750 mg film-coated tablets.
Levetiracetam Tiefenbacher 1000 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. See section 4.

What is in this leaflet:

1. What Levetiracetam Tiefenbacher is and what it is used for
2. What you need to know before you take Levetiracetam Tiefenbacher
3. How to take Levetiracetam Tiefenbacher
4. Possible side effects
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1. What Levetiracetam Tiefenbacher is and what it is used for

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

Levetiracetam Tiefenbacher 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 Tiefenbacher

Do not take Levetiracetam Tiefenbacher:

- 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 before taking Levetiracetam Tiefenbacher

- 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 Tiefenbacher 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 Tiefenbacher:

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

Taking Levetiracetam Tiefenbacher with food, drink and alcohol:

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

Levetiracetam Tiefenbacher 750 mg tablets contain Sunset Yellow FCF (E110) Sunset Yellow FCF (E110) coloring agent which may cause allergic reactions. The other strengths of Levetiracetam Tiefenbacher tablets do not contain this ingredient.

3. How to take Levetiracetam Tiefenbacher

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 Tiefenbacher 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 and 3000 mg each day.

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

Example: if your daily dose is 1000 mg, you might take 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 3000 mg each day.

Example: if your daily dose is 1000 mg, you might take 2 tablets of 250 mg in the morning and 2 tablets of 250 mg 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 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.

Example: a general dose of 20 mg per kg bodyweight each day, you must give your 25 kg child 1 tablet of 250 mg in the morning and 1 tablet of 250 mg in the evening

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 Tiefenbacher tablets with a sufficient quantity of liquid (*e.g.* a glass of water).

Duration of treatment:

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

If you take more Levetiracetam Tiefenbacher than you should:

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

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 Tiefenbacher:

If stopping treatment, as with other antiepileptic medicines, Levetiracetam Tiefenbacher 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 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, 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;
- liver function test abnormal;
- 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 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 the national reporting system [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Levetiracetam Tiefenbacher

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 bottle/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 Tiefenbacher contains

The active substance is called levetiracetam.

250 mg

Each tablet contains 250 mg levetiracetam.

The other ingredients are:

Tablet core: Maize Starch, Povidone (K30), Magnesium stearate, Colloidal anhydrous silica.

Film-coating: Polyvinyl Alcohol-Partially Hydrolyzed, Titanium Dioxide (E171), Macrogol 3350, Talc (E553b), Indigo Carmine Aluminium Lake (E132)

500 mg

Each tablet contains 500 mg levetiracetam.

The other ingredients are:

Tablet core: Maize Starch, Povidone (K30), Magnesium stearate, Colloidal anhydrous silica.

Film-coating: Polyvinyl Alcohol-Partially Hydrolyzed, Titanium Dioxide (E171), Macrogol 3350, Talc (E553b), Iron Oxide Yellow (E172)

750 mg

Each tablet contains 750 mg levetiracetam.

The other ingredients are:

Tablet core: Maize Starch, Povidone (K30), Magnesium stearate, Colloidal anhydrous silica.

Film-coating: Polyvinyl Alcohol-Partially Hydrolyzed, Titanium Dioxide (E171), Macrogol 3350, Talc (E553b), Sunset Yellow FCF Aluminium Lake (E110), Iron Oxide Red (E172)

1000 mg

Each tablet contains 1000 mg levetiracetam.

The other ingredients are:

Tablet core: Maize Starch, Povidone (K30), Magnesium stearate, Colloidal anhydrous silica.

Film-coating: Polyvinyl Alcohol-Partially Hydrolyzed, Titanium Dioxide (E171), Macrogol 3350, Talc (E553b),

What Levetiracetam Tiefenbacher looks like and contents of the pack

250 mg: The film-coated tablets are blue coloured, capsule shaped tablets with deep notch on one side.

500 mg: The film-coated tablets are yellow coloured, capsule shaped tablets with deep notch on one side.

750 mg: The film-coated tablets are orange coloured, capsule shaped tablets with deep notch on one side.

1000 mg: The film-coated tablets are white coloured, capsule shaped tablets with deep notch on one side.

Levetiracetam Tiefenbacher film-coated tablets are supplied in blister packs and bottles.

Blister packs contain 10, 20, 30, 50, 60, 90, 100, 120 and 200 film-coated tablets.

Bottles contain 10, 20, 30, 50, 60, 90, 100, 120 and 200 film-coated tablets.

Not all pack sizes may be marketed.

Marketing authorisation holder

[To be completed nationally.]

Manufacturer

[To be completed nationally.]

This medicinal product is authorised in the Member States of the European Economic Area (EEA) under the following names:

[To be completed nationally]

This leaflet was last revised in May 2014.