

PACKAGE LEAFLET: INFORMATION FOR THE USER

TINALVO

500mg film-coated tablets, 1000mg film-coated tablets

LEVETIRACETAM

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 TINALVO is and what it is used for
2. Before you take TINALVO
3. How to take TINALVO
4. Possible side effects
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1. WHAT TINALVO IS AND WHAT IS IT USED FOR

TINALVO 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. BEFORE YOU TAKE TINALVO

Do not take TINALVO

- If you are allergic to levetiracetam, pyrrolidone derivatives or any of the other ingredients of this medicine.
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Warnings and precautions

Talk to your doctor before taking TINALVO

- 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 TINALVO have had thoughts of harming or killing themselves. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor.

Children and adolescents

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

Other medicines and TINALVO

Tell your doctor or pharmacist

- if you are taking, have recently taken or might take any other medicines.

Do not take macrogol (a drug used as laxative) for one hour before and one hour after taking levetiracetam as this may result in a loss of its effect.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

TINALVO should not be used during pregnancy unless clearly necessary. A risk of birth defects for your unborn child cannot be completely excluded. TINALVO 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

TINALVO 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 TINALVO

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

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

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

Monotherapy

- **Dose in adults and adolescents (from 16 years of age):**
General dose: between 1000 mg and 3,000 mg each day.
When you will first start taking TINALVO, 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, your reduced starting dose is 1 tablet of 500 mg in the morning and 1 tablet of 500 mg 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 and 3,000 mg each day.
Example: if your daily dose is 1,000 mg, you might take 1 tablet of 500 mg in the morning and 1 tablet of 500 mg in the evening.
- **Dose in infants (1 month 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 TINALVO 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 50kg and when tablets don't allow accurate dosage.

Method of administration

Swallow TINALVO tablets with a sufficient quantity of liquid (e.g. a glass of water). You may take TINALVO with or without food.

Duration of treatment

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

The possible side effects of an overdose of TINALVO 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 TINALVO:

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 TINALVO:

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

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.

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 user in 10 people

- nasopharyngitis;
- somnolence (sleepiness), headache.

Common: may affect 1 to 10 users in 100 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 1 to 10 users in 1000 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 1 to 10 users in 10,000 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);
- uncontrollable muscle spasms affecting the head, torso and limbs, difficulty in controlling movements, hyperkinesia (hyperactivity);
- pancreatitis;
- liver 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. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE TINALVO

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.

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.