PACKAGE LEAFLET:
INFORMATION FOR THE USER

TAD Pharma
MEMBER OF KRKA GROUP

Leve TAD®

500 mg film-coated tablets

Levetiracetam

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT LEVE TAD IS AND WHAT IT IS USED FOR

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

Leve TAD is used:
- on its own in patients 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 patients from one month of age
  - myoclonic seizures in patients from 12 years of age with juvenile myoclonic epilepsy
  - primary generalised tonic-clonic seizures in patients from 12 years of age with idiopathic generalised epilepsy

2. BEFORE YOU TAKE LEVE TAD

Do not take Leve TAD:
- If you are allergic (hypersensitive) to levetiracetam or any of the other ingredients of Leve TAD.

Take special care with Leve 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 antiepileptics such as Leve TAD 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:
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Leve TAD with food and drink:
You may take Leve TAD with or without food. As a safety precaution, do not take Leve 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.
Leve TAD should not be used during pregnancy unless clearly necessary. The potential risk to your unborn child is unknown. Leve 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:
Leve TAD may impair your ability to drive or operate any tools or machinery, as Leve 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 LEVE TAD

Always take Leve TAD exactly as your doctor has told you. You should check with your doctor if you are not sure.
Leve 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 1,000 mg (2 tablets) and 3,000 mg (6 tablets) each day.

When you will first start taking Leve 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 weight and dose. An oral solution and Leve TAD 250 mg tablets are presentations more appropriate to infants and young children.

Dose in infants (1 month to less than 6 months):
An oral solution is a presentation more appropriate to infants.

Method of administration:
Swallow Leve TAD tablets with a sufficient quantity of liquid (e.g. a glass of water).

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

If you take more Leve TAD than you should:
The possible side effects of an overdose of Leve 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 Leve 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 Leve TAD:
If stopping treatment, as with other antiepileptic medicines, Leve TAD should be discontinued gradually to avoid an increase of seizures.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Leve TAD can cause side effects, although not everybody gets them.
Tell your doctor if you have any of the following and they worry you.

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.

The frequency of possible side effects listed below is defined using the following convention:

Very common (affects more than 1 user in 10)

Common (affects 1 to 10 users in 100)

Uncommon (affects 1 to 10 users in 1,000)

Rare (affects 1 to 10 users in 10,000)

Very rare (affects less than 1 user in 10,000)

Not known (frequency cannot be estimated from the available data)

Very common:
- somnolence (sleepiness);
- asthenia/fatigue (tiredness).

Common:
- infection, nasopharyngitis;
- decreased number of blood platelets;
- anorexia (loss of appetite), weight increase
- agitation, depression, emotional instability/mood swings, hostility or aggression, insomnia, nervousness or irritability, personality disorders (behavioural problems), thinking abnormal (slow thinking, unable to concentrate);
- dizziness (sensation of unsteadiness), convulsion, headache, hyperkinesia (hyperactivity), ataxia (impaired coordinated movements), tremor (involuntary trembling), amnesia (loss of memory), balance disorder (equilibrium disorder), disturbance in attention (loss of concentration), memory impairment (forgetfulness);
- diplopia (double vision), vision blurred;
- vertigo (sensation of rotation);
- cough (increase of pre-existing cough);
- abdominal pain, nausea, dyspepsia (indigestion), diarrhoea, vomiting;
- rash, eczema, pruritus;
- myalgia (muscle pain);
- accidental injury.

Not known:
- decreased number of red blood cells, and/or white blood cells;
- weight loss;
- abnormal behaviour, anger, anxiety, confusion, hallucination, mental disorder, suicide, suicide attempt and suicidal ideation;
- paraesthesia (tingling);
- pancreatitis, hepatic failure, hepatitis, liver function test abnormal;
- hair loss, blistering of the skin, mouth, eyes and genital area, skin eruption.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE LEVE TAD

Keep out of the reach and sight of children.

Do not use 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.

6. FURTHER INFORMATION

What Leve 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 Leve 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 100 film-coated tablets.

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