

Levetiracetam-AFT 100 mg/mL Oral Solution

Levetiracetam 100 mg/mL

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What Levetiracetam-AFT is used for

Levetiracetam-AFT 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.

How Levetiracetam-AFT works

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

Levetiracetam-AFT may be used alone, or in combination with other medicines, to treat your condition.

Before you use Levetiracetam-AFT

- When you must not use it

Do not take Levetiracetam-AFT if you are allergic to any of the ingredients listed at the end of this leaflet.

Levetiracetam-AFT oral solution contains maltitol. Maltitol may cause diarrhoea or have a laxative effect. Do not use this medicine if you have hereditary problems of fructose intolerance.

Do not take this medicine after the expiry date (EXP) printed on the pack.

Do not take this medicine if the solution is not clear or the bottle shows signs of tampering.

If this medicine has expired or is damaged, return it to your pharmacist for disposal.

Pregnancy and lactation

Tell your doctor if you are pregnant or intend to become pregnant.

Levetiracetam-AFT may affect your developing baby if you take it during pregnancy. However, it is very important to control your seizures while you are pregnant. Your doctor will outline and weigh up all the risks and benefits of taking Levetiracetam-AFT during pregnancy to help decide whether or not you should take it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

The active ingredient in Levetiracetam-AFT passes into breast milk and there is a possibility that your baby may be affected. Your doctor will discuss the risks and benefits of using Levetiracetam-AFT if you are breastfeeding.

- Before you start use it

Tell your doctor if you have allergies to any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or valproate).

Tell your doctor if you have or have had any medical conditions, especially kidney or liver problems.

- Taking other medicines

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

Levetiracetam-AFT does not interact with the oral contraceptive pill.

However, you may be given Levetiracetam-AFT together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptive. Your doctor may advise you to use an additional method of contraception if you take Levetiracetam-AFT with other antiepileptic medicines.

How to use Levetiracetam-AFT

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Your doctor will tell you how much Levetiracetam-AFT you will need to take each day. This may depend on your age, your condition and whether or not you are taking any other medicines.

Your doctor may start you on a low dose of Levetiracetam-AFT first. Your doctor will slowly increase the amount of medicine until you are taking enough to control your epilepsy and you are not having seizures.

- How to use it

Use the syringe provided in the cardboard box to measure the exact quantity of oral solution prescribed by your doctor. Since the syringe is marked in terms of milligrams (mg), the dose prescribed in milligrams (mg) can be directly measured using the syringe. In case the dose is prescribed in milliliter (mL), refer to the following conversion:

$$1 \text{ mL} = 100 \text{ mg}$$

Levetiracetam-AFT oral solution may be diluted in a glass of water or baby's bottle.

1. Open the bottle by pressing the cap and turning it anticlockwise.
2. Dip the syringe into the bottle and withdraw the prescribed dose.
3. Empty the contents of the syringe in a glass of water or baby's bottle.
4. Drink the whole contents of the glass/baby's bottle.
5. Close the bottle with the plastic screw cap.
6. Wash the syringe with water only.

- When to use it

Take Levetiracetam-AFT twice a day, once in the morning and once at night. Take it at about the same time each day.

Taking your medicine at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

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- How long to use it

Continue taking Levetiracetam-AFT for as long as your doctor recommends.

- If you forget to use it

Contact your doctor if you have missed one or more doses.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- 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.

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 *Levetiracetam-AFT*.

Tell your doctor immediately if you become pregnant while taking this medication.

Tell your doctor immediately if you notice an increase in seizures.

Tell your doctor immediately if you have symptoms of depression or thoughts of harming yourself.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Levetiracetam-AFT to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you. Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic medicines, Levetiracetam-AFT may cause dizziness or drowsiness in some people. This is more frequent at the beginning of treatment or after an increase in the dose.

If you are feeling dizzy or drowsy do not drive, operate machinery, or do anything else that could be dangerous. Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling dizzy or drowsy.

Be careful when drinking alcohol while taking this medicine. Combining Levetiracetam-AFT and alcohol can make you more drowsy.

Side effects

Like all medicines, Levetiracetam-AFT 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.

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking this medicine, even if you think the problems are not connected with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- Dizziness
- Feeling weak
- Headache
- Common cold
- Upset stomach
- Diarrhea
- Feeling tired, drowsy or sleepy

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability
- feelings of depression
- upper respiratory tract infections
- weight loss

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- thoughts of harming yourself
- more frequent or more severe seizures
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, mouth, throat or tongue or other parts of the body
- rash, itching or hives on the skin
- 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 muscleache, 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.

The above list includes very serious side effects. You may need urgent medical attention or hospitalization.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers →

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Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Levetiracetam-AFT

- Storage

Keep Levetiracetam-AFT oral solution in its original bottle until it is time to take it.

If you take the solution out of the bottle it may not keep well.

Keep your oral solution in a cool place where the temperature stays below 30 °C. After opening the bottle, the oral solution must be stored below 25 °C and used within 7 months.

You should write the date of opening the bottle on the bottle label, and the discard date.

Keep out of the reach and sight of children.

Do not store any medicine in the bathroom, or near a sink, or on a window sill.

Do not leave it in the car especially on hot days. Heat and dampness can destroy medicines.

Do not use your medicine after the expiry date which is stated on the pack after 'EXP'. The expiry date refers to the last day of that month.

- 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

Levetiracetam-AFT oral solution is available in a 100 mg/mL strength and is supplied in an amber bottle with a child resistant cap. It is also supplied with a measuring syringe for dosing.

- Ingredients

- Active ingredient

Levetiracetam

- Inactive ingredients

- sodium citrate
- citric acid monohydrate

- methylhydroxybenzoate
- parahydroxybenzoate
- ammonium glycyrrhizate
- glycerol
- maltitol solution
- acesulfame potassium
- grape flavour

- MAL number:

MAL*****

Manufacturer

One Pharma Industrial Pharmaceutical Company S.A.
60th km N.N.R. Anthinon-Lamias
32009 Schimatari Voiotias
GREECE

Product Registration Holder

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