

Levetiracetam-AFT oral solution

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Levetiracetam-AFT?

Levetiracetam-AFT contains the active ingredient levetiracetam. Levetiracetam-AFT is used to control epilepsy.

For more information, see Section [1. Why am I using Levetiracetam-AFT?](#) in the full CMI.

2. What should I know before I use Levetiracetam-AFT?

Do not use if you have ever had an allergic reaction to levetiracetam or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Levetiracetam-AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Levetiracetam-AFT and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Levetiracetam-AFT?

- Follow all directions given to you by your doctor carefully.
- 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.

More instructions can be found in Section [4. How do I use Levetiracetam-AFT?](#) in the full CMI.

5. What should I know while using Levetiracetam-AFT?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Levetiracetam-AFT.• Tell your doctor immediately if you notice an increase in seizures or have symptoms of depression or thoughts of harming yourself.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking Levetiracetam-AFT, or change the dosage, without checking with your doctor.• Do not give Levetiracetam-AFT to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how Levetiracetam-AFT affects you.• If you are feeling dizzy or drowsy do not drive, operate machinery, or do anything else that could be dangerous.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking this medicine.• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep your oral solution in a place where the temperature stays below 30 °C.• After opening the bottle, the oral solution must be used within 7 months.

For more information, see Section [5. What should I know while using Levetiracetam-AFT?](#) in the full CMI.

6. Are there any side effects?

Some common/less serious side effects include dizziness, headache, common cold, upset stomach. However, some very serious side effects include thoughts of harming yourself, more frequent or more severe seizures, shortness of breath, swelling of the face, lips, mouth, throat or tongue or other parts of the body, rash, itching or hives on the skin.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Levetiracetam-AFT oral solution

Active ingredient(s): *levetiracetam*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Levetiracetam-AFT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Levetiracetam-AFT.**

Where to find information in this leaflet:

- [1. Why am I using Levetiracetam-AFT?](#)
- [2. What should I know before I use Levetiracetam-AFT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use Levetiracetam-AFT?](#)
- [5. What should I know while using Levetiracetam-AFT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Levetiracetam-AFT?

Levetiracetam-AFT contains the active ingredient **levetiracetam**. 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.

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.

Your doctor may have prescribed this medicine in addition to your current therapy.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

There is no evidence that this medicine is addictive.

The safety and effectiveness of Levetiracetam-AFT has not been established in patients less than 4 years of age.

2. What should I know before I use Levetiracetam-AFT?

Warnings

Do not use Levetiracetam-AFT if:

you are allergic to levetiracetam, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath.
- wheezing or difficulty breathing.
- swelling of the face, lips, tongue or other parts of the body.
- rash, itching or hives on the skin.

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 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.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Check with 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)
- have allergies to any other substances, such as foods, preservatives or dyes.
- have or have had any medical conditions, especially kidney problem or liver problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with 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.

If you become pregnant while taking this medicine, tell your doctor.

Talk to your doctor if you are breastfeeding or intend 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.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking Levetiracetam-AFT.

3. What if I am taking other medicines?

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

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.

4. How do I use Levetiracetam-AFT?

How much to take

- Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.
- 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.
- The dose dispensing syringe is graduated (marked) in terms of milligrams (mg). One milliliter (mL) of Levetiracetam-AFT oral solution contains 100 mg of levetiracetam therefore, 100 mg mark on the syringe scale is equivalent to 1 mL of solution.
- For patients 12 years of age and older, the dosage is generally between 1000 mg (10 mL) and 3000 mg (30 mL) each day, taken in two doses.
- For children 4 to 11 years of age the doctor will calculate the dosage based on the child's weight and tell you how much to give. The medicine is to be given twice daily.
- 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.

If you do not understand the instructions on the pack, ask your doctor or pharmacist for help.

When to take Levetiracetam-AFT

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.

How to take 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 mL = 100 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.

How long to take it

Most antiepileptics take time to work, so do not be discouraged if you do not feel better straight away.

Continue taking your medicine for as long as your doctor tells you to.

This medicine helps control your condition but does not cure it. Therefore, you must take your medicine every day, even if you feel well.

If you forget to use Levetiracetam-AFT

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 Levetiracetam-AFT

If you think that you have used too much Levetiracetam-AFT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Symptoms of an overdose may include feeling drowsy.

5. What should I know while using Levetiracetam-AFT?

Things you should do

Tell your doctor immediately if:

- you notice an increase in seizures.
- you have symptoms of depression or thoughts of harming yourself.
- you feel Levetiracetam-AFT is not helping your condition. Your doctor may need to change your medicine.
- for any reason, you have not taken this medicine exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.

Remind any doctor, dentist or pharmacist you visit that you are using Levetiracetam-AFT. If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking Levetiracetam-AFT. Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Levetiracetam-AFT.

Be sure to keep all of your doctor's appointments so that your progress can be checked.

Your doctor will check your progress and may want to take some tests from time to time. This helps to prevent unwanted side effects.

Things you should not do

- Do not stop taking Levetiracetam-AFT, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays. Stopping Levetiracetam-AFT suddenly may cause unwanted side effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.
- Do not give Levetiracetam-AFT to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not give this medicine to anyone with a fructose intolerance. It may cause a serious side effect.
- Do not take Levetiracetam-AFT to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Levetiracetam-AFT affects you.

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.

Drinking alcohol

Be careful when drinking alcohol while taking this medicine.

Tell your doctor if you drink alcohol.

Combining Levetiracetam-AFT and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with Levetiracetam-AFT.

Looking after your medicine

- 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 place where the temperature stays below 30 °C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it. A locked cupboard at least one and-a-half meters above the ground is a good place to store medicines.

When to discard your medicine (as relevant)

After opening the bottle, the oral solution must be used within 7 months.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Levetiracetam-AFT.

This medicine helps most people with epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them. If you get any side effects, do not stop taking Levetiracetam-AFT without first talking to your doctor or pharmacist.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• dizziness• feeling weak• headache• common cold• upset stomach• diarrhoea• feeling tired, drowsy or sleepy	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>This list includes the more common side effects of your medicine. They are usually mild and short-lived.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability• feeling of depression• upper respiratory tract infections• weight loss	<p>Tell your doctor as soon as possible if you notice any of these serious side effects.</p> <p>These side effects that may require medical attention.</p>

Very serious side effects

Very serious side effects	What to do
<ul style="list-style-type: none">• 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	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</p> <p>You may need urgent medical attention or hospitalisation.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Levetiracetam-AFT contains

Active ingredient (main ingredient)	levetiracetam
Other ingredients (inactive ingredients)	sodium citrate citric acid monohydrate methylhydroxybenzoate parahydroxybenzoate ammonium glycyrrhizate glycerol maltitol solution acesulfame potassium grape flavour

Do not take this medicine if you are allergic to any of these ingredients.

What Levetiracetam-AFT 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. (Aust R 218279).

Who distributes Levetiracetam-AFT

AFT Pharmaceuticals Pty Ltd.
Suite 301, 113 Wicks Road
North Ryde, NSW 2113, Australia

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