

APO-Levetiracetam (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 APO-Levetiracetam oral solution?

APO-Levetiracetam oral solution contains the active ingredient levetiracetam. APO-Levetiracetam oral solution is used to control epilepsy.

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

2. What should I know before I use APO-Levetiracetam oral solution?

Do not start treatment 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 or pharmacist 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 APO-Levetiracetam oral solution?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Levetiracetam oral solution 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 APO-Levetiracetam oral solution?

- Your doctor will decide how much APO-Levetiracetam oral solution you will receive. This depends on your age, your condition and whether or not you are taking any other medicines.

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

5. What should I know while using APO-Levetiracetam oral solution?

Things you should do	<ul style="list-style-type: none">Call your doctor straight away if you notice an increase in seizures; have symptoms of depression or thoughts of harming yourself; or if you become pregnant while being given this medicine.Remind any doctor, nurse, dentist or pharmacist who is treating you that you are being given this medicine.
Things to be careful of	<ul style="list-style-type: none">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	<ul style="list-style-type: none">Combining APO-Levetiracetam oral solution and alcohol can make you more drowsy.Your doctor may suggest you avoid alcohol while you are being treated with this medicine.
Looking after your medicine	<ul style="list-style-type: none">Keep APO-Levetiracetam oral solution in a cool place where the temperature stays below 25°C. Protect from light.Keep APO-Levetiracetam oral solution in its original bottle until it is time to take it.

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

6. Are there any side effects?

Common side effects include: dizziness; feeling weak; headache; common cold, stomach complaints; feeling tired, drowsy or sleepy;. Serious side effects include changes in behaviour, thinking or mood (e.g. thoughts of harming yourself); upper respiratory tract infections; weight loss; more frequent or more severe seizures; and allergic type reactions. Do not be alarmed by this list. You may not experience any of them.

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.

APO-Levetiracetam (oral solution)

Active ingredient(s): levetiracetam

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Levetiracetam oral solution. **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 APO-Levetiracetam oral solution.**

Where to find information in this leaflet:

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

1. Why am I using APO-Levetiracetam oral solution?

APO-Levetiracetam oral solution contains the active ingredient levetiracetam. APO-Levetiracetam oral solution 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.

APO-Levetiracetam oral solution 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.

APO-Levetiracetam oral solution 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.

2. What should I know before I use APO-Levetiracetam oral solution?

Warnings

You must not be given APO-Levetiracetam oral solution if:

- you are allergic to levetiracetam, or any of the ingredients listed at the end of this leaflet.

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

Always check the ingredients to make sure you can use this medicine.

- the expiry date (EXP) printed on the pack has passed. If you are given this medicine after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor, nurse or pharmacist.

Check with your doctor if you:

- have any allergies to:
 - any other medicines, especially barbiturates (such as phenobarbitone) or any other antiepileptic medicines (such as carbamazepine, lamotrigine or valproate)
 - any other substances, such as foods, preservatives or dyes.
- have or have had any other medical conditions especially the following:
 - kidney problems (renal damage, renal insufficiency, impaired renal function);
 - liver problems
- have hereditary problems of fructose intolerance. APO-Levetiracetam oral solution contains maltitol.
- take any medicines for any other condition.

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.

APO-Levetiracetam oral solution may affect your developing baby if you are given 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, and help you to decide whether or not you should be take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

The active ingredient in APO-Levetiracetam oral solution passes into breast milk and there is a possibility that your baby may be affected.

Your doctor will discuss the risks and benefits of the treatment and the importance of breastfeeding.

If you have not told your doctor about any of the above, tell them before you are given APO-Levetiracetam oral solution.

Use in children

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

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.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while you are being given APO-Levetiracetam oral solution.

APO-Levetiracetam oral solution does not interact with the oral contraceptive pill.

However, you may be given APO-Levetiracetam oral solution 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 are given APO-Levetiracetam oral solution with other antiepileptic medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APO-Levetiracetam oral solution.

4. How do I use APO-Levetiracetam oral solution?

How much to take

- Your doctor will decide how much APO-Levetiracetam oral solution you should take. This depends on your age, your condition and whether or not you are taking any other medicines.
- 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, your doctor will calculate the dosage based on your 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 APO-Levetiracetam oral solution 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.

- You may experience a bitter taste after taking APO-Levetiracetam oral solution.
- Follow the instructions provided and use APO-Levetiracetam oral solution until your doctor tells you to stop.

When to take APO-Levetiracetam oral solution

- APO-Levetiracetam oral solution must be taken twice a day - once in the morning and once in the evening - at about the same time each day.
- Taking APO-Levetiracetam oral solution 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 APO-Levetiracetam oral solution before or after food.

How long to take APO-Levetiracetam oral solution for

- Continue taking APO-Levetiracetam oral solution for as long as your doctor tells you. This medicine helps control your condition, but does not cure it. Therefore you must take your medicine every day, even if you feel well.
- Most anticonvulsant medicines take time to work, so do not be discouraged if you do not feel better straight away.

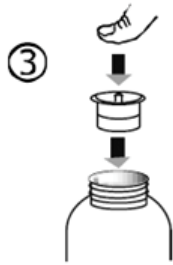
How to take APO-Levetiracetam oral solution

- Use the syringe provided in the box to measure the exact quantity of APO-Levetiracetam oral solution prescribed by your doctor.
 - APO-Levetiracetam oral solution may be diluted in a glass of water or baby's bottle.
 - Follow the instructions below to take APO-Levetiracetam oral solution:
1. Open the bottle, press the cap down and turn it anticlockwise (Figure 1).

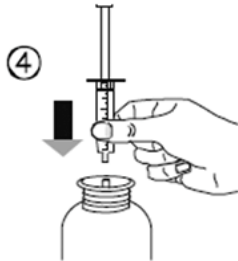


2. Separate the adaptor from the syringe (Figure 2). Insert the adaptor into the bottle neck (Figure 3). Ensure it is firmly attached.

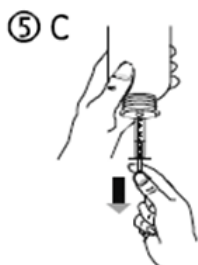
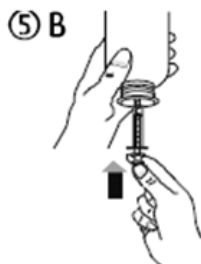
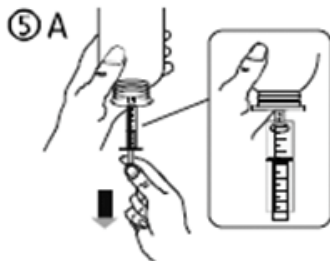




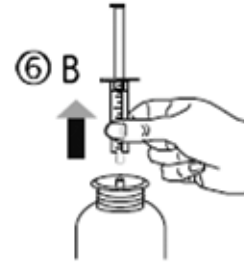
3. Take the syringe and put it in the adaptor opening (Figure 4). Turn the bottle upside down (Figure 5).



4. Fill the syringe with a small amount of solution by pulling the piston down (Figure 5A), then push the piston upward in order to remove any possible bubbles (Figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (Figure 5C).



5. Turn the bottle the right way up (Figure 6A). Remove the syringe from the adaptor (Figure 6B).



6. Empty the contents of the syringe in a glass of water or baby's bottle by pushing the piston to the bottom of the syringe (Figure 7).



7. Drink the whole contents of the glass/baby's bottle. Close the bottle with the plastic screw cap. Wash the syringe with water only (Figure 8).



If you forget to take APO-Levetiracetam oral solution

APO-Levetiracetam oral solution should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you take too much APO-Levetiracetam oral solution

If you think you have used too much APO-Levetiracetam oral solution, you may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy.

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.

5. What should I know while using APO-Levetiracetam oral solution?

Things you should do

- Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking APO-Levetiracetam oral solution.
- Tell your doctor if you feel APO-Levetiracetam oral solution is not helping your condition. Your doctor may need to change your medicine.
- Tell your doctor if, for any reason, you have not taken APO-Levetiracetam solution exactly as prescribed. Otherwise, your doctor may change your treatment unnecessarily.
- 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.

Call your doctor straight away if you:

- notice an increase in seizures.
- have symptoms of depression or thoughts of harming yourself.
- become pregnant while taking APO-Levetiracetam oral solution.

Remind any doctor, dentist or pharmacist you visit that you are using APO-Levetiracetam oral solution. Tell them that you are using APO-Levetiracetam oral solution:

- before starting on any new medicine;
- before any surgery and/or emergency treatment.

Things you should not do

- Do not stop taking APO-Levetiracetam oral solution, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays. Do not stop using this medicine suddenly as it 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 use APO-Levetiracetam oral solution if you have hereditary problems of fructose intolerance. APO-Levetiracetam oral solution contains maltitol.
- Do not give APO-Levetiracetam oral solution to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not give APO-Levetiracetam oral solution to anyone with fructose intolerance. It may cause a serious side effect.
- Do not take APO-Levetiracetam oral solution 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 APO-Levetiracetam oral solution affects you.

As with other antiepileptic medicines, APO-Levetiracetam oral solution 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

Tell your doctor if you drink alcohol.

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

Looking after your medicine

- Keep APO-Levetiracetam 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.
- Store below 25°C. Protect from light.
- After opening the bottle, the APO-Levetiracetam oral solution must be used within 7 months.
- You should write the date of opening the bottle label, and the discard date.

Follow the instructions on 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.

Keep it where young children cannot reach it.

When to discard your medicine (as relevant)

If your doctor tells you to stop taking this medicine, ask your pharmacist what to do with any medicine that is left over.

Getting rid of any unwanted medicine

If you no longer need to use 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?

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.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are treated with APO-Levetiracetam oral solution.

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

If you get any side effects, do not stop the treatment with APO-Levetiracetam oral solution 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.	Speak to your doctor if you have any of these less serious side effects and they worry you.

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.• Feelings of depression.• Thoughts of harming yourself.• Upper respiratory tract infections.• Weight loss.• More frequent or more severe seizures.• Symptoms of an allergic reaction:<ul style="list-style-type: none">○ shortness of breath, wheezing or difficulty breathing;○ swelling, blistering or peeling skin around the face, lips, mouth, throat or tongue or other parts of the body;○ rash, itching or hives on the skin.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

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.

Sometimes you may have side effects without experiencing any symptoms. It is important to keep your routine doctor's appointments so that your condition can be checked.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to 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 APO-Levetiracetam oral solution contains

Active ingredient (main ingredient)	Levetiracetam
Other ingredients (inactive ingredients)	Glycerol Propyl hydroxybenzoate Methyl hydroxybenzoate Ammonium glycyrrhizinate Citric acid monohydrate Sodium citrate dihydrate Acesulfame potassium Maltitol Natural flavouring type grapefruit (ARTG 110209)
Potential allergens	Propyl hydroxybenzoate Methyl hydroxybenzoate Maltitol

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

What APO-Levetiracetam oral solution looks like

APO-Levetiracetam oral solution is a clear, colourless solution supplied in a 100 mL amber glass bottle with a child resistant cap. A measuring syringe and adaptor are also included in the pack for dosing.(AUST R 237435)

Who distributes APO-Levetiracetam oral solution

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in April 2025.