

APO-Levetiracetam

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?

APO-Levetiracetam contains the active ingredient levetiracetam. APO-Levetiracetam is used to control epilepsy. For more information, see Section [1. Why am I using APO-Levetiracetam?](#) in the full CMI.

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

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 APO-Levetiracetam?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Levetiracetam 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?

- For patients 12 years of age and older, the dosage is generally between 1000 mg and 3000 mg 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.

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

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

Things you should do	<ul style="list-style-type: none">• 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 should not do	<ul style="list-style-type: none">• Do not give APO-Levetiracetam to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.• Do not take APO-Levetiracetam to treat any other complaints unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• 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.
Drinking alcohol	<ul style="list-style-type: none">• Be careful when drinking alcohol while taking this medicine.
Looking after your medicine	<ul style="list-style-type: none">• Keep your tablets in the pack until it is time to take them.• Keep your tablets in a cool dry place where the temperature stays below 25°C.

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

6. Are there any side effects?

Common side effects include: dizziness, feeling weak, headache, common cold, upset stomach, diarrhoea, feeling tired, drowsy or sleepy.

Serious side effects include: mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability, feelings of depression, upper respiratory tract infections, weight loss.

Very serious side effects include: thoughts of harming yourself, more frequent or more severe seizures, shortness of breath, wheezing or difficulty breathing, swelling, blistering or peeling skin around the face, lips, mouth, throat, tongue, genitals 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.

APO-Levetiracetam

Levetiracetam (*LEE ve tye RA se tam*)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using APO-Levetiracetam?

APO-Levetiracetam contains the active ingredient **levetiracetam**. APO-Levetiracetam is an antiepileptic, it works by controlling brain chemicals which send signals to nerves so that seizures do not happen.

APO-Levetiracetam 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.

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

Warnings

Do not use APO-Levetiracetam 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.
- **if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.** 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 any other medical conditions
 - kidney problems
 - liver problems.

- take any medicines for any other condition
- Tell your doctor or pharmacist if you have 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.

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 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 APO-Levetiracetam during pregnancy to help decide whether or not you should take it.

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

The active ingredient in APO-Levetiracetam 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 APO-Levetiracetam if you are breastfeeding.

APO-Levetiracetam and oral contraceptives

APO-Levetiracetam does not interact with the oral contraceptive pill. However, you may be given APO-Levetiracetam 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 APO-Levetiracetam with other antiepileptic medicines.

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.

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.

4. How do I use APO-Levetiracetam?

How much to take

- Your doctor will tell you how much APO-Levetiracetam 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.
- For patients 12 years of age and older, the dosage is generally between 1000 mg and 3000 mg 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 APO-Levetiracetam 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.
- Follow the instructions provided and use APO-Levetiracetam until your doctor tells you to stop.

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

When to take APO-Levetiracetam

- APO-Levetiracetam should be used 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 APO-Levetiracetam

- Swallow the tablets whole with a glass of water.

If you forget to use APO-Levetiracetam

APO-Levetiracetam should be used regularly at the same time each day.

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.

- Contact your doctor if you have missed one or more doses.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

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

If you use too much APO-Levetiracetam

If you think that you have used too much Levetiracetam-WGR, 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.

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

Things you should do

Call your doctor straight away if you:

- notice an increase in seizures
- have symptoms of depression or thoughts of harming yourself.
- feel APO-Levetiracetam is not helping your condition.
- become pregnant while taking this medicine

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking APO-Levetiracetam.

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking Levetiracetam-WGR.

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.

Tell your doctor if, for any reason, you have not taken this medicine exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily. Remind any doctor, dentist, pharmacist or dentist you visit that you are using APO-Levetiracetam.

Things you should not do

- Do not stop taking APO-Levetiracetam, 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 give APO-Levetiracetam to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not take APO-Levetiracetam 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 affects you. Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic medicines, APO-Levetiracetam 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.

Alcohol may make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with APO-Levetiracetam.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack they will not keep well.
- Store below 25°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.

Keep it where young children cannot reach it.

When to discard your medicine

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.

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

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 	<p>Speak to your doctor if you have any of these less serious side effects</p>

<ul style="list-style-type: none"> • feeling tired, drowsy or sleepy. 	<p>effects and they worry you.</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 • feelings of depression • upper respiratory tract infections • weight loss. 	<p>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.</p>

Very serious side effects

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, blistering or peeling skin around the face, lips, mouth, throat, tongue, genitals or other parts of the body • rash, itching or hives on the skin, drug reaction with eosinophilia and systemic symptoms (DRESS). • Unusual heart rate 	<p>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.</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 APO-Levetiracetam contains

<p>Active ingredient (main ingredient)</p>	<p>Levetiracetam</p>
<p>Other ingredients (inactive ingredients)</p>	<p>croscarmellose sodium, magnesium stearate, silica</p>

	colloidal anhydrous, povidone, starch maize
--	--

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

What APO-Levetiracetam looks like

- APO-Levetiracetam 250mg tablet is light blue, capsule shaped, biconvex film coated tablets plain on both sides (Aust R 296940)
- APO-Levetiracetam 500mg is yellow, capsule shaped, biconvex film coated tablets plain on both sides (Aust R 296941)
- APO-Levetiracetam 1000mg is white, capsule shaped, biconvex film coated tablets plain on both sides (Aust R 296942).

Who distributes APO-Levetiracetam

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

Australia

www.arrotex.com.au

This leaflet was prepared in March 2025