

APO-Levetiracetam Oral Solution

Contains the active ingredient levetiracetam

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about APO-LEVETIRACETAM oral solution.

It does not contain all of the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking APO-LEVETIRACETAM oral solution against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What this medicine is used for

APO-LEVETIRACETAM oral solution is used to control epilepsy.

Epilepsy is a condition where you have repeated seizures (fits). There are many different types of seizures, ranging from mild to severe.

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

Your doctor may have prescribed APO-LEVETIRACETAM oral solution in addition to your current therapy.

Ask your doctor if you have any questions about why APO-LEVETIRACETAM oral solution has been prescribed for you.

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

APO-LEVETIRACETAM oral solution is available only with a doctor's prescription.

There is no evidence that APO-LEVETIRACETAM oral solution is addictive.

Before you take this medicine

When you must not take it

Do not take APO-LEVETIRACETAM oral solution if you have an allergy to levetiracetam or any of the ingredients listed at the end of this leaflet.

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.

APO-LEVETIRACETAM oral solution contains maltitol. Do not use this medicine if you have hereditary problems of fructose intolerance.

If you are unsure whether any of the above conditions apply to you, ask your doctor.

Do not take APO-LEVETIRACETAM oral solution if the expiry date (Exp.) printed on the pack has passed.

Do not take APO-LEVETIRACETAM oral solution if the packaging is torn or shows signs of tampering.

Before you start to take 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)
- any other substances, such as foods, preservatives or dyes.

Tell your doctor if you have, or have had, any medical conditions, especially the following:

- kidney problems (renal damage, renal insufficiency, impaired renal function)
- liver problems.

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

APO-LEVETIRACETAM oral solution 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 oral solution during pregnancy to help decide whether or not you should take it.

Tell your doctor if you are breastfeeding or wish 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 taking APO-LEVETIRACETAM oral solution when breastfeeding.

If you have not told your doctor about any of the above, tell them before you start taking APO-LEVETIRACETAM oral solution.

Taking other medicines

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

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 drugs that do interact and they may compromise contraceptive efficacy. Your doctor may advise you to use an additional method of

contraception if you take APO-LEVETIRACETAM oral solution with other antiepileptic drugs.

How to take this medicine

How much to take

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

Your doctor will tell you how much APO-LEVETIRACETAM oral solution 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 1,000mg (10 mL) and 3,000mg (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 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.

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

How to take APO-LEVETIRACETAM oral solution

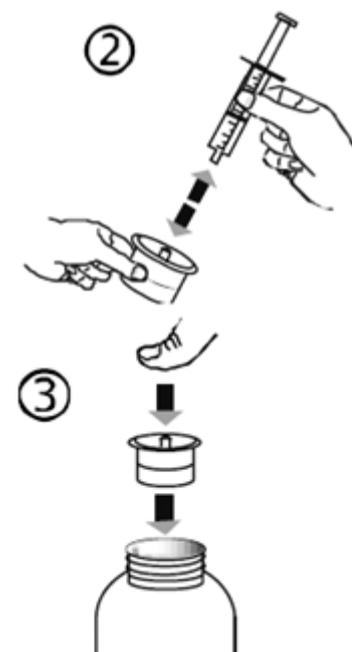
Use the syringe provided in the cardboard box to measure the exact quantity of oral solution prescribed by your doctor.

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

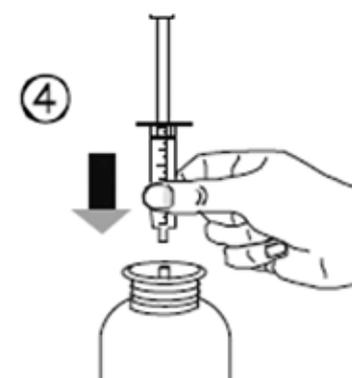
To open the bottle, press the cap and turn it anticlockwise (figure 1)



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

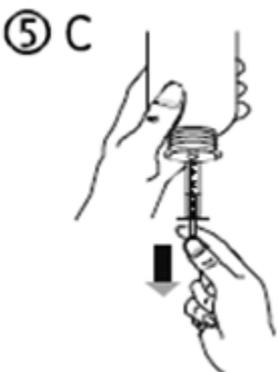
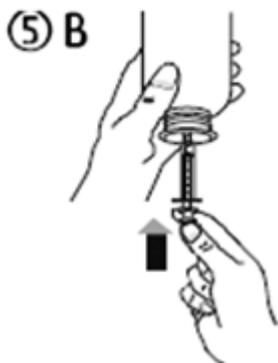
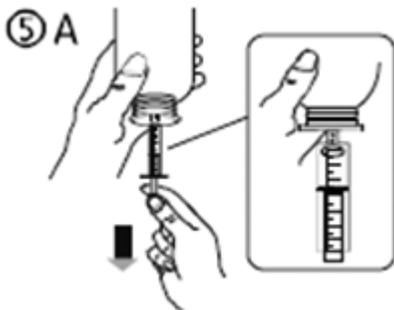


Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).

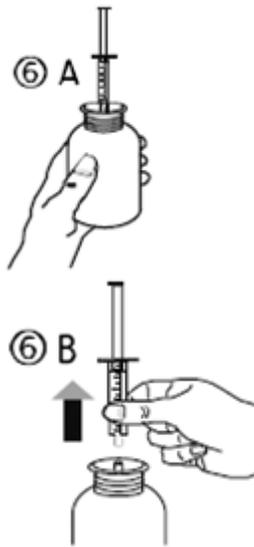




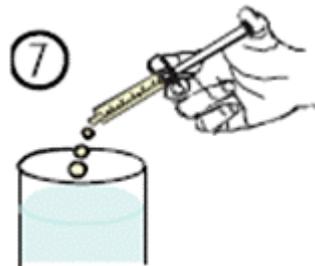
Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



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

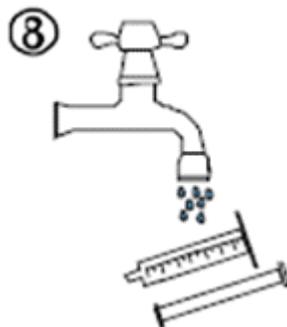


Empty the contents of the syringe in a glass of water or baby's bottle by pushing the piston to the bottom of the syringe (figure 7).



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).



When to take it

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 it for

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

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.

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.

Stopping APO-LEVETIRACETAM oral solution suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

If you forget to take it

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

Do not take a double dose to make up for the dose 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 take too much (overdose)

Immediately telephone your doctor, or the Poisons Information

Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much APO-LEVETIRACETAM oral solution. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include feeling drowsy.

While you are taking this medicine

Things you must do

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

Tell your doctor immediately if you have symptoms of depression or thoughts of self-harm.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking APO-LEVETIRACETAM oral solution.

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

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 oral solution exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking APO-LEVETIRACETAM oral solution, tell your doctor.

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 must not do

Do not give APO-LEVETIRACETAM oral solution to anyone else, even if they have the same condition as you.

Do not give this medicine to anyone with fructose intolerance.

It may cause serious side effect.

Do not stop taking APO-LEVETIRACETAM oral solution unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how APO-LEVETIRACETAM oral solution affects you. Children should be careful doing things like riding bicycles or climbing trees.

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.

Be careful when drinking alcohol while taking APO-LEVETIRACETAM oral solution.

Combining APO-LEVETIRACETAM oral solution and alcohol can make you drowsier. Your doctor may suggest you avoid alcohol while you are being treated

with APO-LEVETIRACETAM oral solution.

Possible side effects

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

This medicine helps most people with epilepsy, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

If you get any side effects, do not stop taking APO-LEVETIRACETAM oral solution without first talking to your doctor or pharmacist.

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

- dizziness
- feeling weak
- headache
- common cold
- upset stomach
- diarrhoea
- feeling tired, drowsy or sleepy

These are the more common side effects of APO-LEVETIRACETAM oral solution. Mostly these are 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, stop taking APO-LEVETIRACETAM oral solution and tell your doctor immediately, or go to Accident and Emergency at the 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.

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

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

Allergic reactions

If you think you are having an allergic reaction to levetiracetam, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

Storage and disposal

Storage

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.

Keep APO-LEVETIRACETAM oral solution in a cool place where the temperature stays below 25°C and 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.

Do not store APO-LEVETIRACETAM oral solution or any other medicine in the bathroom or near a sink.

Do not leave APO-LEVETIRACETAM oral solution in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep APO-LEVETIRACETAM oral solution where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking APO-LEVETIRACETAM oral solution, or your medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product description

What APO-LEVETIRACETAM oral solution looks like

APO-LEVETIRACETAM oral solution is available in 100 mg/mL strength and is supplied in an amber glass bottle with a child resistant cap.

A measuring syringe and adaptor are also included in the pack for dosing.

Ingredients

The active ingredient in APO-LEVETIRACETAM oral solution is levetiracetam, 100 mg/mL.

The solution also contains:

- glycerol
- propylhydroxybenzoate
- methylhydroxybenzoate
- ammonium glycyrrhizate
- citric acid monohydrate
- sodium citrate
- acesulfame potassium
- maltitol solution
- natural flavouring type grapefruit (ARTG 110209)

Australian Registration Numbers

APO-LEVETIRACETAM oral solution (bottle):

AUST R 237435.

Sponsor

Southern Cross Pharma Pty Ltd
56 Illabunda Drive
Malua Bay NSW 2536
Australia

Distributor

Apotex Pty Ltd
16 Giffnock Avenue
Macquarie Park NSW 2113

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This leaflet was last updated in April 2016