

LEVETIRACETAM GH Oral Solution

contains the active ingredient levetiracetam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LEVETIRACETAM GH.

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 LEVETIRACETAM GH 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 LEVETIRACETAM GH is used for

LEVETIRACETAM GH 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.

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

Your doctor may have prescribed LEVETIRACETAM GH in addition to your current therapy.

Ask your doctor if you have any questions about why LEVETIRACETAM GH has been prescribed for you.

The safety and effectiveness of LEVETIRACETAM GH have not been established in patients less than 4 years of age.

LEVETIRACETAM GH is available only with a doctor's prescription.

There is no evidence that LEVETIRACETAM GH is addictive.

Before you take LEVETIRACETAM GH

When you must not take it

Do not take LEVETIRACETAM GH 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.

LEVETIRACETAM GH 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 LEVETIRACETAM GH if the expiry date (Exp.) printed on the pack has passed.

Do not take LEVETIRACETAM GH 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.

LEVETIRACETAM GH 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 GH 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 LEVETIRACETAM GH 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 LEVETIRACETAM GH when breastfeeding.

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

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.

LEVETIRACETAM GH does not interact with the oral contraceptive pill. However, you may be given LEVETIRACETAM GH 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 LEVETIRACETAM GH with other antiepileptic drugs.

How to take LEVETIRACETAM GH

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 LEVETIRACETAM GH 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 (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 GH 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 LEVETIRACETAM GH oral solution.

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

How to take LEVETIRACETAM GH

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

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

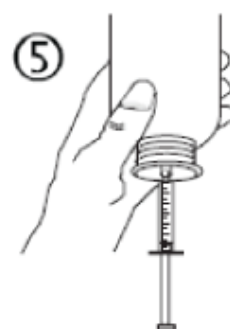
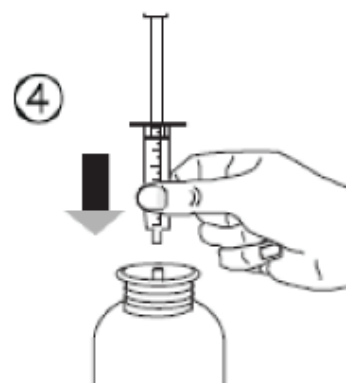
Open the bottle, press the cap and turn it anticlockwise (figure 1).



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

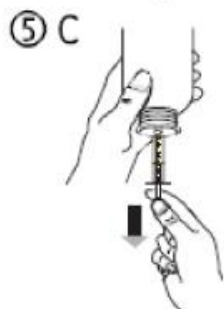
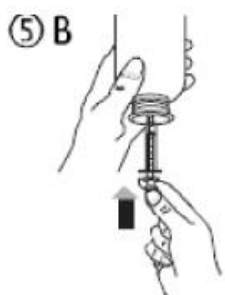
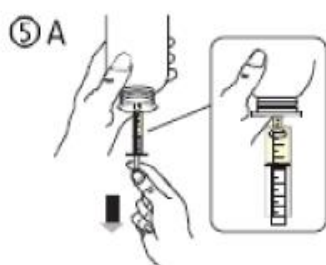


Take the syringe and put it in the adaptor opening (figure 4). Turn the bottle upside down (figure 5).

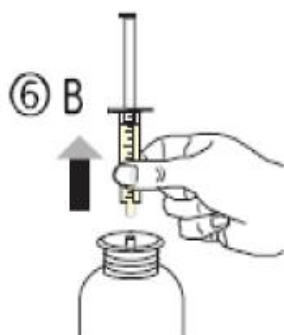


Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upward in order to remove any possible bubbles (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in

millilitres (ml) prescribed by your doctor (figure 5C).



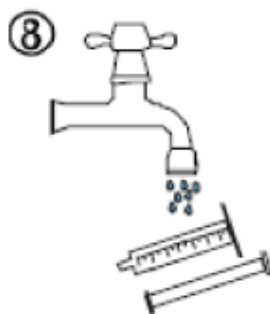
Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



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 LEVETIRACETAM GH

LEVETIRACETAM GH must be taken twice a day, once in the morning and once in the evening, at about the same time each day. Taking LEVETIRACETAM GH 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 LEVETIRACETAM GH before or after food.

If you forget to take LEVETIRACETAM GH

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.

How long to take LEVETIRACETAM GH for

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

**Continue taking
LEVETIRACETAM GH 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
LEVETIRACETAM GH, 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 GH 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 take too much LEVETIRACETAM GH (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 LEVETIRACETAM GH. 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 LEVETIRACETAM GH

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 LEVETIRACETAM GH.

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

Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking LEVETIRACETAM GH.

Tell your doctor if you feel LEVETIRACETAM GH is not helping your condition.

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking LEVETIRACETAM GH, 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 LEVETIRACETAM GH 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 LEVETIRACETAM GH unless your doctor tells you to.

Do not take LEVETIRACETAM GH oral solution to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

As with other antiepileptic medicines, LEVETIRACETAM GH 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 LEVETIRACETAM GH.

Combining LEVETIRACETAM GH and alcohol can make you drowsier. Your doctor may suggest you avoid alcohol while you are being treated with LEVETIRACETAM GH.

Possible Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LEVETIRACETAM GH.

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.

Do not be alarmed by the following list of side effects. You may not experience any of them.

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

If you get any side effects, do not stop taking LEVETIRACETAM GH 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 LEVETIRACETAM GH. 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 LEVETIRACETAM GH 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, 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.

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.

After using LEVETIRACETAM GH

Storage

Keep LEVETIRACETAM GH 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 LEVETIRACETAM GH solution in a cool place where the temperature stays below 25°C and protect from light.

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

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

Do not store LEVETIRACETAM GH or any other medicine in the bathroom or near a sink.

Do not leave LEVETIRACETAM GH in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep LEVETIRACETAM GH 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 LEVETIRACETAM GH, or your medicine has passed its expiry date, ask your pharmacist what to do with any that is left over.

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 LEVETIRACETAM GH 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)

Supplier

Southern Cross Pharma Pty Ltd
Suite 5/118 Church Street
Hawthorn VIC 3122
Australia

Distributor

Generic Health Pty Ltd
Suite 2, Level 2
19-23 Prospect Street
Box Hill VIC 3128
Email: ghinfo@generichealth.com.au
Phone: +613 9809 7900
Website: www.generichealth.com.au

Australian registration number:

LEVETIRACETAM GH - AUST R
237436

Date of preparation: April 2020.

Product description

What it looks like

LEVETIRACETAM GH oral solution is available in a 100 mg/mL