

Levetiracetam-GH Tablets 250 mg, 500 mg and 1000 mg

Levetiracetam.
(Lupin Australia Pty. Ltd.)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Levetiracetam-GH Tablets 250 mg, 500 mg and 1000 mg. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Levetiracetam-GH Tablets 250 mg, 500 mg and 1000 mg against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

WHAT LEVETIRACETAM-GH TABLETS 250 mg, 500 mg and 1000 mg IS USED FOR

Levetiracetam-GH Tablets 250 mg, 500 mg and 1000 mg 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 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 Tablets may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe Levetiracetam-GH Tablets in addition to your current therapy.

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

There is no evidence that Levetiracetam-GH Tablets is addictive.

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

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

BEFORE YOU TAKE LEVETIRACETAM-GH TABLETS 250 mg, 500 mg AND 1000 mg.

When you must not take it

Do not take Levetiracetam-GH Tablets if you have an allergy to:

- any of the ingredients listed at the end of this leaflet

Symptoms of an allergic reaction to Levetiracetam-GH Tablets 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

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

Do not take Levetiracetam-GH Tablets if you are pregnant or intend to become

pregnant, without talking to your doctor first.

Like most antiepileptic medicines, Levetiracetam-GH Tablets is not recommended for use during pregnancy. However, it is very important to control your fits while you are pregnant. If it is necessary for you to take Levetiracetam-GH Tablets, your doctor can help you decide whether or not to take it during pregnancy.

Do not breastfeed while taking Levetiracetam-GH Tablets. It passes into breast milk.

Do not take Levetiracetam-GH Tablets after the expiry date (EXP) printed on the pack.

Do not take Levetiracetam-GH Tablets if the packaging is torn or shows signs of tampering or if the tablets do not look quite right.

If Levetiracetam-GH Tablets has expired or is damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking Levetiracetam-GH Tablets, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, especially barbiturates or any other anticonvulsant medicines
- 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 intend to become pregnant.

Levetiracetam-GH Tablets may affect your developing baby if you take it during pregnancy.

However, it is very important to control your fits while you are pregnant.

If it is necessary for you to take Levetiracetam-GH Tablets, your doctor can help you decide whether or not to take it during pregnancy.

Tell your doctor if you are breast-feeding or plan to breast-feed.

It is recommended that you do not breastfeed while taking Levetiracetam-GH Tablets.

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

TAKING OTHER MEDICINES

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

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

HOW TO TAKE LEVETIRACETAM-GH TABLETS

HOW MUCH TO TAKE

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

For children 4 to 11 years of age the dose is 20 mg/kg to 60 mg / kg each day.

There is no data to support the use of Levetiracetam-GH Tablets for patients less than 4 years of age.

Your doctor will tell you how much Levetiracetam-GH Tablets 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.

Your doctor may recommend that you start with a low dose of Levetiracetam-GH Tablets and slowly increase the dose to the lowest amount needed to control your epilepsy /seizures (fits).

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you believe that the effect of Levetiracetam-GH Tablets is too weak, talk to your doctor.

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

How to take it

Levetiracetam-GH Tablets

Swallow Levetiracetam-GH Tablets whole with a glass of water.

When to take it

Levetiracetam-GH Tablets must be taken two times a day, once in the morning and once in the evening, at about the same time each day.

Taking Levetiracetam-GH Tablets at the same time each day will have the best effect. It will also help you remember when to take the tablets/oral solution.

It does not matter if you take Levetiracetam-GH Tablets before or after food.

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 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.

How long to take it

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

Continue taking Levetiracetam-GH Tablets for as long as your doctor tells you to.

Levetiracetam-GH Tablets help 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 Tablets, 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 Tablets 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 (overdose)

Immediately telephone your doctor if you think that you or anyone else may have taken too much Levetiracetam-GH Tablets. Do this even if there are no signs of discomfort or poisoning.

If you take too much Levetiracetam-GH Tablets you may feel drowsy.

WHILE YOU ARE USING LEVETIRACETAM-GH TABLETS

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 Tablets.

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

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

Tell your doctor if you feel Levetiracetam-GH Tablets 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 Tablets exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking Levetiracetam-GH Tablets, 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 Tablets to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not take Levetiracetam-GH Tablets to treat any other complaints unless your doctor tells you to.

Do not stop using it unless your doctor tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how Levetiracetam-GH Tablets affects you.

As with other anticonvulsant medicines, Levetiracetam-GH Tablets may cause drowsiness in some people.

This is more frequent at the beginning of treatment or at dosage increase.

Make sure you know how you react to Levetiracetam-GH Tablets before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy.

Children should not ride a bike, climb trees or do anything else that could be dangerous if they are feeling drowsy or sleepy.

Levetiracetam-GH Tablets may cause drowsiness and affect alertness.

Be careful when drinking alcohol while taking Levetiracetam-GH Tablets.

Combining Levetiracetam-GH Tablets and alcohol can make you more drowsy.

Your doctor may suggest you avoid alcohol while you are being treated with Levetiracetam-GH Tablets.

SIDE EFFECTS

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

Levetiracetam-GH Tablets help 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 treatment 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 Levetiracetam-GH Tablets 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
- common cold and upper respiratory tract infections
- feeling tired, drowsy or sleepy

These are the more common side effects of Levetiracetam-GH Tablets. Mostly these are mild and short-lived.

Other side-effects reported include:

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability.

You may not experience any of these side-effects.

If you experience any other side-effects, tell your doctor immediately.

If you experience more frequent or more severe seizures (fits), or thoughts of self harm tell your doctor immediately or go to Accident and Emergency at your nearest hospital.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

Some of these side effects can only be found when your doctor does tests from time to time to check your progress.

AFTER USING LEVETIRACETAM-GH TABLETS

Storage

Keep your tablets in the pack until it is time to take it.

If you take the tablets out of their pack they will not keep well.

Keep your tablets in a cool dry place where the temperature stays below 30 °C.

Do not store Levetiracetam-GH Tablets or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

Heat and dampness can destroy some medicines.

Keep it 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 or pharmacist tells you to stop taking Levetiracetam-GH Tablets or they have passed their expiry date, ask your pharmacist what to do with any that is left over.

PRODUCT DESCRIPTION

Levetiracetam-GH Tablets

What it looks like

Levetiracetam-GH Tablets are available in four strengths:

250mg - Blue, oblong -shaped, biconvex film-coated tablets, debossed with '250' on one side and score line on the other side.

500mg - yellow, oblong-shaped, biconvex film-coated tablets, debossed with '500' on one side and score line on the other side.

1000mg - White to off white, Oblong - shaped, biconvex film-coated tablets, debossed with '1000' on one side and score line on the other side.

Levetiracetam 250mg, 500mg and 1000mg tablets are packed in blister packs, pack sizes of 60 Tablets.

Ingredients

Active ingredient

Each Levetiracetam-GH Tablet contains 250 mg, 500mg and 1000 mg of Levetiracetam as the active ingredient.

The inactive ingredients in Levetiracetam-GH include:

- Starch - maize
- Silica-colloidal anhydrous
- Croscarmellose sodium
- Povidone
- Cellulose - Microcrystalline
- Talc-purified
- Magnesium stearate

Tablets are film-coated & the coating for each tablet strength contains polyvinyl alcohol, macrogol 6000 and macrogol 3350, talc - purified and titanium dioxide (E 171).

The following strengths also contain:

- 250mg - Indigo carmine CI73015
- 500mg - Iron oxide yellow CI77492

Levetiracetam-GH Tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Australian Register Numbers:

250mg Tablets AUST R 161294

500mg Tablets AUST R 161295

1000mg Tablets AUST R 161296

SUPPLIER:

Levetiracetam-GH Tablets is distributed in Australia by:

Generic Health Pty Ltd
Suite 1 1175 Toorak Road
Camberwell VIC 3124
Australia

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