

LEVETIRACETAM GENERIC HEALTH

Levetiracetam Tablets

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take this medicine. This leaflet answers some common questions about levetiracetam. 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 risks and benefits. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking levetiracetam against the risks this medicine could 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 is Levetiracetam Generic Health used for

Levetiracetam Generic Health is used for the control of epilepsy in adults and children.

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

Levetiracetam (the active ingredient in Levetiracetam Generic Health) 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 may be used alone, or in combination with other medicines, to treat your condition.

Your doctor may prescribe levetiracetam in addition to your current therapy.

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

Levetiracetam is not known to be addictive.

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

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

Before you take

Levetiracetam Generic Health

Do not take if you have an allergy to:

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

Symptoms of an allergic reaction to levetiracetam 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 if you are pregnant or intend to become pregnant, without talking to your doctor first.

Like most antiepileptic medicines, levetiracetam 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, your doctor can help you decide whether or not to take it during pregnancy.

Do not breastfeed while taking levetiracetam.

Levetiracetam passes into breast milk.

Do not take the tablets after the expiry date (EXP) printed on the pack.

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

If the tablet has expired or is damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, 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 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, your doctor can help you decide whether or not to take it during pregnancy.

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

It is recommended that you do not breastfeed while taking this medicine.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking this medicine.

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 does not interact with the oral contraceptive pill. However, you may be given levetiracetam 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 this medicine with other antiepileptic drugs

How do I take this medicine

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 for patients less than 4 years of age.

Your doctor will tell you how 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 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 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

Swallow the tablets whole with a glass of water. It 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 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 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 for

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

Continue taking levetiracetam for as long as your doctor tells you to.

Levetiracetam 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, 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 suddenly may cause unwanted effects or make your condition worse. Your doctor will slowly reduce your dose before you can stop taking it completely.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor if you think that you or anyone else may have taken too much levetiracetam.

Do this even if there are no signs of discomfort or poisoning.

In Australia call 13 11 26 for Poisons Information Centres. **Keep telephone numbers for these places handy.**

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

If you take too much levetiracetam you may feel drowsy.

While you are taking levetiracetam

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.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking levetiracetam. Before you have any surgery or emergency treatment, tell your doctor or dentist that you are taking levetiracetam.

Tell your doctor if you feel levetiracetam 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 exactly as prescribed.

Otherwise, your doctor may change your treatment unnecessarily.

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

Do not take levetiracetam 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 affects you.

As with other anticonvulsant medicines, levetiracetam 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 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 may cause drowsiness and affect alertness.

Be careful when drinking alcohol while taking levetiracetam.

Combining levetiracetam and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with levetiracetam.

What are the side effects?

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

Levetiracetam 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 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 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. Mostly these are mild and short-lived.

Other side-effects reported include:

- mood changes such as depression, nervousness,

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 taking levetiracetam tablets

Keep levetiracetam tablets where children cannot reach them such as in a locked cupboard.

Keep levetiracetam tablets in the container that they were supplied in until time to take them.

Store levetiracetam tablets below 30°C.

Do not leave in a car, on a window sill or in the bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

What Levetiracetam Generic Health tablets look like

Levetiracetam Generic Health film-coated tablets come in 3 different strengths:

Levetiracetam Generic Health levetiracetam 250 mg are blue coloured, oval shaped, film-coated tablets debossed with breakline separating '250' and 'MG' on one side and '1014' on other side. AUST R 159047

Levetiracetam Generic Health/ levetiracetam 500 mg are yellow coloured, oval shaped, film-coated tablets debossed with breakline separating '500' and 'MG' on one side and '1015' on other side. AUST R 159048

Levetiracetam Generic Health levetiracetam 1000 mg are white to off white, oval shaped, film-coated tablets debossed with breakline separating '1000' and 'MG' on one side and '1017' on other side. AUST R 159049

Levetiracetam Generic Health tablets are available in packs of 60 tablets

Ingredients

The active ingredient in Levetiracetam Generic Health tablet is levetiracetam. Each tablet contains 250 mg, 500 mg, or 1000 mg of levetiracetam.

Each tablet also contains the following excipients: maize starch, povidone, purified talc, colloidal anhydrous silica, magnesium stearate.

250 mg tablet coating: hypromellose, titanium dioxide, macrogol 400, indigo carmine CI73015.

500 mg tablet coating: hypromellose, titanium dioxide, macrogol 400 and iron oxide yellow CI77492.

1000 mg tablet coating: hypromellose, macrogol 400 and titanium dioxide .

Levetiracetam Generic Health tablets do not contain gluten or lactose.

Sponsor

Torrent Australasia Pty Ltd
100 George St,
Parramatta, NSW 2150
AUSTRALIA

Supplier

Generic Health Pty Ltd
Suite 1, Level 1
1175 Toorak Rd
Camberwell VIC 3124
AUSTRALIA

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

This leaflet was prepared in April 2010.