

Levitaccord Tablets 250 mg/500 mg/1000 mg

(Levetiracetam tablets 250mg/500 mg/1000 mg)

levetiracetam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Levitaccord tablets.

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 Levitaccord tablets 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 Levitaccord Tablets are used for

Levitaccord tablets are 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.

Levitaccord tablets belong 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.

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

Your doctor may have prescribed Levitaccord tablets in addition to your current therapy.

Ask your doctor if you have any questions about why this Levitaccord tablets have been prescribed for you.

There is no evidence that Levitaccord tablets are addictive.

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

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

Before you take Levitaccord Tablets

When you must not take it

Do not take Levitaccord tablets if you have an allergy to:

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

Some of the 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

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

Do not take Levitaccord tablets if the packaging is torn or shows

signs of tampering or if the tablets do not look quite right.

If Levitaccord tablets have expired or are damaged, return to your pharmacist for disposal.

If you are not sure whether you should start taking Levitaccord 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 (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
- liver problems

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

Levitaccord tablets 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 Levitaccord tablets during pregnancy to help decide whether or not you should take it.

Tell your doctor if you are breastfeeding or plan to breastfeed.

The active ingredient in Levitaccord tablets 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 Levitaccord tablets if you are breastfeeding.

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

Taking other medicines

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

Levitaccord tablet does not interact with the oral contraceptive pill.

However, you may be given Levitaccord tablets together with other antiepileptic medicines that do interact and may affect the effectiveness of your contraceptives.

Your doctor may advise you to use an additional method of contraception if you take Levitaccord tablets with other antiepileptic medicines.

How to take Levitaccord Tablets

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

Your doctor will tell you how much Levitaccord 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 medicine.

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 Levitaccord tablets first and 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 it

Swallow the Levitaccord tablet whole with a glass of water.

When to take it

Take Levitaccord tablet twice a day, once in the morning and once at night. Take it, at about the same time each day.

Taking Levitaccord tablet at the same time each day will have the best effect. It will also help you remember when to take the tablets.

It does not matter if you take Levitaccord tablet 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 antiepileptic medicines take time to work, so do not be discouraged if you do not feel better straight away.

Continue taking Levitaccord tablet for as long as your doctor tells you to.

Levitaccord tablet 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 Levitaccord tablet, or change the dosage, without checking with your doctor. Do not let yourself run out of medicine over the weekend or on holidays.

Stopping Levitaccord tablet 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 or the Poisons Information Centre (the telephone number in Australia is 13 11 26 and in New Zealand is 0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Levitaccord tablet. 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 using Levitaccord Tablets

Things you must do

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.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking Levitaccord tablet.

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

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

Tell your doctor if you feel Levitaccord tablet is not helping your condition.

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

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

Do not take Levitaccord tablet 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 Levitaccord tablet affects you. Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic medicines, Levitaccord tablet 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 Levitaccord tablet.

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

Side effects

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

Levitaccord tablet 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.

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 Levitaccord tablet 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
- lethargy
- muscular weakness

The above list includes the more common side effects of Levitaccord tablet. They are usually 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,

panic attack, 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, tell your doctor immediately or go to Accident and Emergency at your 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 urgent medical attention or hospitalisation.

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.

After using Levitaccord Tablets

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Levitaccord tablet 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 tells you to stop taking Levitaccord tablet or expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Levitaccord Tablets 250 mg - White to off white, oval biconvex, film-coated tablets, debossed 'L 64' and breakline on one side and plain on the other side.

Levitaccord Tablets 500 mg - Yellow coloured, oval biconvex, film-coated tablets, debossed 'L 65' and breakline on one side and plain on the other side.

Levitaccord Tablets 1000 mg - White to off white, oval biconvex, film-coated tablets, debossed 'L 67' and breakline on one side and plain on the other side.

Levitaccord Tablets 250/500/1000 mg tablets are available in blister packs of 60 tablets.

Ingredients

Active ingredient(s):

- Levitaccord Tablets 250 mg - contain 250 mg of Levetiracetam as the active ingredient.
- Levitaccord Tablets 500 mg - contain 500 mg of Levetiracetam as the active ingredient.
- Levitaccord Tablets 1000 mg - contain 1000 mg of Levetiracetam as the active ingredient.

Other ingredients:

carmellose sodium, povidone, colloidal anhydrous silica and magnesium stearate.

Levitaccord tablets are film-coated. The coating for each tablet strength contains polyvinyl alcohol, macrogol, talc and titanium dioxide. The following strength also contains:

- 500 mg - iron oxide yellow (C177492).

Levitaccord tablets do not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Name and Address of the Sponsor

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