

APO-Levetiracetam

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 levetiracetam. 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 using this medicine 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 want to read it again.

What this medicine is used for

Levetiracetam 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 in nature.

How it works

Levetiracetam belongs to a group of medicines called antiepileptics. It is thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

This medicine 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 this medicine has been prescribed for you.

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

There is not enough information to recommend the use of this medicine in children under the age of 4 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- levetiracetam
- 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, throat or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

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

If you are not sure whether you should start taking this medicine, talk to your doctor.

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 of the following medical conditions:

- kidney problems
- liver problems
- depression

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

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

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

The active ingredient in Keppra 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 Keppra if you are breastfeeding.

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

Taking other medicines

Tell your doctor if you are taking any other medicines, including any

that you get from your pharmacy, supermarket or health food shop.

Some medicines and levetiracetam may interfere with each other. These include:

- other antiepileptic drugs

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with levetiracetam.

How to take this medicine

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

They may differ to the information contained in this leaflet.

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

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

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

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 Keppra 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.

How to take it

Swallow the tablets whole with a glass of water.

When to take it

This medicine must be taken two times a day, once in the morning and once in the evening, at about the same time each day.

Taking it 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 it with or without food.

How long to take it for

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

Continue taking your medicine for as long as your doctor tells you.

This medicine helps control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

Make sure you have enough to last over weekends and holidays.

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

Stopping Keppra suddenly may cause unwanted side 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 missed doses.

This may increase the chance of you experiencing side effects.

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 to help you remember.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine.

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

You may need urgent medical attention.

If you take too much levetiracetam, you may feel drowsy.

While you are taking this medicine

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.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor, if for any reason, you have not taken this medicine exactly as prescribed, or if you feel this medicine is not helping your condition.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not stop taking your medicine or change the dosage without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

Children should be careful doing things like riding bicycles or climbing trees.

This medicine may cause dizziness or drowsiness or affect alertness in some people. This is more frequent at the beginning of treatment or at dosage increase. If you have any of these symptoms, 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 this medicine.

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

Side effects

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

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 lists of side effects. You may not experience any of them.

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

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
- hair loss
- feeling tired, drowsy or sleepy.

The above list includes the more common side effects of your medicine.

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 and irritability
- upper respiratory tract infections
- weight loss
- strange involuntary movements.

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, tongue, or other parts of the body; rash, itching or hives on the skin (symptoms of an allergic reaction)
- a fever or flu-like symptoms followed by a widespread skin rash.

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

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

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

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

If you take your medicine out of the pack it may not keep well.

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

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep this medicine 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

250 mg tablets: Light blue, capsule shaped, biconvex, film-coated tablets, plain on both sides. Blister packs of 60 tablets. AUST R 296940.

500 mg tablets: Yellow, capsule shaped, biconvex, film-coated tablets, plain on both sides. Blister packs of 60 tablets. AUST R 296941.

1000 mg tablets: White, capsule shaped, biconvex, film-coated tablets, plain on both sides. Blister packs of 60 tablets. AUST R 296942.

* Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 250 mg, 500 mg, or 1000 mg levetiracetam as the active ingredient.

It also contains the following:

- croscarmellose sodium
- colloidal anhydrous silica
- povidone
- maize starch
- magnesium stearate
- Opadry complete film coating system 03B50643 BLUE (PI 109251) (250 mg tablet only)
- Opadry complete film coating system 03B52573 YELLOW (PI 109246) (500 mg tablet only)
- Opadry complete film coating system 04F58804 WHITE (PI 11793) (1000 mg tablets only)

This medicine does not contain gluten or lactose.

Sponsor

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
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