

LEVI 250/ 500/ 1000

levetiracetam tablets 250mg/ 500 mg/ 1000 mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LEVI 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 LEVI tablets against the benefits they expect it will have for you.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

Keep this leaflet with the medicine.

You may need to read it again.

What LEVI tablets are used for

LEVI tablets are used to control epilepsy and belong to a group of drugs called antiepileptics.

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

The medicine is thought to work by controlling brain chemicals which send signals to nerves so that seizures do not happen.

LEVI tablets may be used alone or in combination with other drugs to treat your condition.

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

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

There is no evidence that LEVI tablets are addictive.

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

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

Before you take it

When you must not take it

Do not take LEVI tablets if you have an allergy to levetiracetam, any other antiepileptic drug or 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 LEVI tablets after the expiry date (EXP) printed on the pack.

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

If you are not sure whether you should start taking LEVI 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 drugs, especially barbiturates, such as phenobarbitone
- any other antiepileptic drugs, 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.

LEVI 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 LEVI 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 LEVI 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 LEVI 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 LEVI 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.

LEVI tablets does not interact with the oral contraceptive pill. However, you may be given LEVI tablets together with other antiepileptic drugs 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 LEVI tablets with other antiepileptic drugs.

How to take it

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 many LEVI 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.

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 drug is to be given twice daily.

Your doctor may start you on a low dose of LEVI tablets first and slowly increase the amount of drug 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 tablet whole with a glass of water.

When to take it

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

Taking this medicine 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 LEVI 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.

How long to take it

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

Continue taking this medicine for as long as your doctor tells you to. LEVI tablets help control your condition, but do not cure it. You must take it every day, even if you feel well.

Do not stop taking LEVI 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 it 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 (telephone 131 126) for advice, or go to Emergency at the

nearest hospital, if you think that you or anyone else may have taken too many LEVI tablets. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of overdose may include feeling drowsy.

While you are taking it

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 LEVI tablets.

If you are about to be started on any new drug, tell your doctor, dentist or pharmacist that you are taking LEVI tablets.

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

Tell your doctor if you feel LEVI tablets are not helping your condition.

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

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

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

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

Things to be careful of

Be careful driving or operating machinery until you know how LEVI tablets affects you.

As with other antiepileptic drugs, LEVI tablets 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 LEVI tablets.

Combining LEVI tablets and alcohol can make you drowsier. Your doctor may suggest you avoid alcohol while you are being treated with this medicine.

Side effects

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

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 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 LEVI tablets without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following common side effects and they worry you:

- dizziness
- feeling weak
- headache
- common cold
- upset stomach
- diarrhoea
- feeling tired, drowsy or sleepy

They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following serious side effects:

- mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability.
- feelings of depression
- upper respiratory tract infections
- weight loss.

These may require urgent medical attention.

If any of the following serious side effects happen, tell your doctor immediately or go to 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.

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 taking it

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 it 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 LEVI tablets or the expiry date has passed, ask your pharmacist what to do with any tablets that are left over.

Product Description

What it looks like

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

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

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

Available in blister packs of 60 tablets.

Ingredients

Active ingredient:

LEVI 250 - contains 250 mg of levetiracetam.

LEVI 500 - contains 500 mg of levetiracetam

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LEVI 1000 - contains 1000 mg of levetiracetam.

Inactive ingredients:

- croscarmellose sodium
- povidone
- colloidal anhydrous silica
- magnesium stearate
- polyvinyl alcohol
- macrogol
- talc
- titanium dioxide
- iron oxide yellow (C177492) - 500 mg tablet only.

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

Sponsor

Arrow Pharma Pty Ltd
15-17 Chapel Street
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Australia

Australian registration numbers:

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LEVI 500: AUST R 168792

LEVI 1000: AUST R 168794

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