

# LEVI 250/ 500/ 1000 (LEVETIRACETAM) TABLETS

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using LEVI?

LEVI tablet contains the active ingredient Levetiracetam. LEVI is used to in epileptic patients aged 4 years and older, initially as add-on therapy, in the treatment of partial onset seizures with or without secondary generalisation.

Monotherapy in the treatment of partial onset seizures, with or without secondary generalisation, in patients from 16 years of age with newly diagnosed epilepsy.

For more information, see Section [1. Why am I using LEVI?](#) in the full CMI.

### 2. What should I know before I use LEVI?

Do not use if you have ever had an allergic reaction to LEVI or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use LEVI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with LEVI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use LEVI?

- The film coated tablets must be taken orally, swallowed with liquid and may be taken with or without food.
- The daily dose is administered in two equally divided doses.

More instructions can be found in Section [4. How do I use LEVI?](#) in the full CMI.

### 5. What should I know while using LEVI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly (if relevant).</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how this medicine affects you. Children should be careful doing things like riding bicycles or climbing trees.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Be careful when drinking alcohol while taking this medicine.</li><li>• Combining LEVI tablets and alcohol can make you more drowsy. Your doctor may suggest you avoid alcohol while you are being treated with LEVI.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your tablets in the pack until it is time to take them.</li><li>• If you take the tablets out of the pack they will not keep well.</li><li>• Keep your tablets in a cool dry place where the temperature stays below 25°C.</li></ul>

For more information, see Section [5. What should I know while using LEVI?](#) in the full CMI.

### 6. Are there any side effects?

Most common side effects are: dizziness, feeling weak, headache, common cold, upset stomach, diarrhoea, feeling tired, drowsy or sleepy.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# LEVI 250/ 500/ 1000 (LEVETIRACETAM) TABLETS

**Active ingredient:** Levetiracetam

## Consumer Medicine Information (CMI)

This leaflet provides important information about using LEVI tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LEVI.**

### Where to find information in this leaflet:

- [1. Why am I using LEVI?](#)
- [2. What should I know before I use LEVI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use LEVI?](#)
- [5. What should I know while using LEVI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using LEVI?

### LEVI contains the active ingredient Levetiracetam.

LEVI is an anti-epileptic medicine.

### LEVI is 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.

This medicine 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.

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

Your doctor may have prescribed this medicine in addition to your current therapy.

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

There is no evidence that this medicine is 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.

## 2. What should I know before I use LEVI?

### Warnings

#### Do not use LEVI if:

- you are allergic to Levetiracetam, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

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 this medicine after the expiry date (EXP) printed on the pack.

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

If this medicine 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 or pharmacist.

### 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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with 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.

Talk to your doctor if you are breastfeeding or intend 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.

### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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 medicines that do interact and may affect the effectiveness of your contraceptive. Your doctor may advise you to use an additional method of contraception if you take LEVI tablets with other antiepileptic medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LEVI tablets.**

### 4. How do I use LEVI?

#### How much to take / use

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 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 medicine is to be given twice daily.

Your doctor may start you on a low dose of LEVI tablets 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.

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

#### How to take

Swallow the tablets whole with a glass of water.

#### When to take LEVI

- Take LEVI tablet twice a day, once in the morning and once at night. Take it at about the same time each day.
- Taking your 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 this medicine before or after food.

#### If you forget to use LEVI

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 your medicine for as long as your doctor tells you to.

This medicine 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 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 LEVI tablets suddenly may cause unwanted side effects or make you condition worse. Your doctor will slowly reduce you dose before you can stop taking it completely.

#### If you use too much LEVI

If you think that you have used too much LEVI tablets, you may need urgent medical attention.

##### You should immediately:

- phone the Poisons Information Centre (by calling **13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

### 5. What should I know while using LEVI?

#### Things you should 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 this medicine.

If you are about to be started on any new medicine, 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 is not helping your condition.

Your doctor may need to change your medicine.

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

Otherwise, your doctor may change your treatment unnecessarily.

If you become pregnant while taking this medicine, 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 should 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 LEVI tablets 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 this medicine affects you. Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic medicines, 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.

### Driving or using machines

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.

### Drinking alcohol

Be careful when drinking alcohol while taking this medicine.

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

### Looking after your medicine

#### Storage

Store LEVI tablets in a cool dry place where temperature stays below 25°C.

Keep your tablets in the blister pack until it is time to take one. If you take the tablets out of the pack they may not keep well.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"><li>• dizziness</li><li>• feeling weak</li><li>• headache</li><li>• common cold</li><li>• upset stomach</li><li>• diarrhoea</li><li>• feeling tired, drowsy or sleepy</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

### Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"><li>• mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability</li><li>• feelings of depression</li><li>• upper respiratory tract infections</li><li>• weight loss</li></ul>	<b>Tell your doctor as soon as possible that may require medical attention</b>
<ul style="list-style-type: none"><li>• thoughts of harming yourself</li><li>• more frequent or more severe seizures</li><li>• shortness of breath</li><li>• wheezing or difficulty breathing</li><li>• swelling of the face, lips, mouth, throat or tongue or other parts of the body rash, itching, or hives on the skin.</li></ul>	<b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side

effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What LEVI contains

<b>Active ingredient (main ingredient)</b>	<b>LEVI 250</b> – contains 250 mg of levetiracetam <b>LEVI 500</b> – contains 500 mg of levetiracetam <b>LEVI 1000</b> – contains 1000 mg of levetiracetam
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"><li>▪ croscarmellose sodium</li><li>▪ povidone</li><li>▪ colloidal anhydrous silica</li><li>▪ magnesium stearate</li><li>▪ polyvinyl alcohol</li><li>▪ macrogol</li><li>▪ talc</li><li>▪ titanium dioxide</li><li>▪ iron oxide yellow (C177492) – 500 mg tablet only.</li></ul>
<b>Potential allergens</b>	-

**Do not take this medicine if you are allergic to any of these ingredients.**

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

### What LEVI tablet 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.

Blister of 60 tablets (Aust R 168790).

#### LEVI 500

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

Blister of 60 tablets (Aust R 168792).

#### 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.

Blister of 60 tablets (Aust R 168794).

## Who distributes LEVI 250/ 500/ 1000

Arrotex Pharmaceuticals Pty Ltd

15 – 17 Chapel Street

Cremorne VIC 3121

Australia

[www.arrotex.com.au](http://www.arrotex.com.au)

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