

# LEVETIRACETAM VIATRIS tablets

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## 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.

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### 1. Why am I using LEVETIRACETAM VIATRIS?

LEVETIRACETAM VIATRIS contains the active ingredient levetiracetam. LEVETIRACETAM VIATRIS is used to control epilepsy.

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

### 2. What should I know before I use LEVETIRACETAM VIATRIS?

Do not use if you have ever had an allergic reaction to levetiracetam 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 LEVETIRACETAM VIATRIS?](#) in the full CMI.

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

Some medicines may interfere with LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS?**

- Your doctor will tell you how much LEVETIRACETAM VIATRIS 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.

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

### **5. What should I know while using LEVETIRACETAM VIATRIS?**

<b>Things you should do</b>
<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using LEVETIRACETAM VIATRIS.</li></ul>

	<ul style="list-style-type: none"> <li>• Notify your doctor straight away if you notice an increase in seizures or if you have thoughts of harming yourself and/or symptoms of mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop using this medicine suddenly or change the dosage unless your doctor tells you to.</li> <li>• Use expired medicine</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how LEVETIRACETAM VIATRIS affects you.</li> <li>• LEVETIRACETAM VIATRIS may cause dizziness or drowsiness in some people. If you are feeling dizzy or drowsy do not drive,</li> </ul>

	operate machinery, or do anything else that could be dangerous.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Tell your doctor if you drink alcohol.</li> <li>• Alcohol combined with taking LEVETIRACETAM VIATRIS may make you drowsy.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store LEVETIRACETAM VIATRIS tablets below 25 °C, in a cool, dry place away from sunlight.</li> </ul>

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

## 6. Are there any side effects?

**Common potential side effects:** dizziness, forgetfulness, loss of concentration, headaches, rash, itchy and dry skin, headache, common cold, upset stomach, diarrhoea, blurred vision, muscle pain, feeling tired, drowsy or sleepy and feeling weak. **Serious potential side effects:** feelings of depression, mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability, more frequent or more severe seizures, allergic reactions (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) and a combination of flu-like symptoms with widespread skin rash and/or high temperatures. 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.

# LEVETIRACETAM VIATRIS tablets

**Active ingredient:** *levetiracetam* (pronounced "LEE ve tye RA se tam")

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using LEVETIRACETAM VIATRIS. **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 LEVETIRACETAM VIATRIS.**

**Where to find information in this leaflet:**

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

## 1. Why am I using LEVETIRACETAM VIATRIS?

**LEVETIRACETAM VIATRIS** contains the active ingredient levetiracetam.

LEVETIRACETAM VIATRIS is an antiepileptic drug.

**LEVETIRACETAM VIATRIS 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.

## 2. What should I know before I use LEVETIRACETAM VIATRIS?

### Warnings

#### **Do not use LEVETIRACETAM VIATRIS 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.

#### **Check with your doctor if you:**

- have any other medical conditions such as kidney or/and liver problems,
- have allergic reactions to any medicines, especially barbiturates (such as phenobarbitone) or any other

antiepileptic medicines (such as carbamazepine, lamotrigine or levetiracetam) or any other substances, such as foods, preservatives or dyes.

- have any other mental health condition, such as depression.

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. LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS if you are breastfeeding.

## **Children and Adolescents**

- LEVETIRACETAM VIATRIS is not recommended for use in children under the age of 4 years as its safety

and effectiveness has not been established in this age group.

- LEVETIRACETAM VIATRIS is used as add on therapy with other medicines to control epilepsy in children 4 years and above.

## **Adolescents and Adults**

- LEVETIRACETAM VIATRIS can be used by itself for patients diagnosed aged 16 years and above. This is dependent on your doctor's decision and on the type of seizures.

### **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.

LEVETIRACETAM VIATRIS does not interact with the oral contraceptive pill.

However, you may be given LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS.**

## **4. How do I use LEVETIRACETAM VIATRIS?**

### **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 LEVETIRACETAM VIATRIS 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 (10 mL) and 3000 mg (30 mL) 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 LEVETIRACETAM VIATRIS 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. Follow the instructions provided and use LEVETIRACETAM VIATRIS until your doctor tells you to stop.

- Most antiepileptics 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.

## **When to take LEVETIRACETAM VIATRIS**

- LEVETIRACETAM VIATRIS should be used 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.

## **How to take LEVETIRACETAM VIATRIS**

Swallow the tablets whole with a glass of water.

## **If you forget to take LEVETIRACETAM VIATRIS**

LEVETIRACETAM VIATRIS should be used regularly at the same time each day.

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 take too much LEVETIRACETAM VIATRIS**

If you think that you have used too much LEVETIRACETAM VIATRIS, 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.

Symptoms of an overdose may include feeling drowsy.

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

## **5. What should I know while using LEVETIRACETAM VIATRIS?**

### **Things you should do**

#### **Call your doctor straight away:**

- If you notice an increase in seizures.
- If you have thoughts of harming yourself and/or symptoms of mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability.

Remind any doctor, dentist or pharmacist you visit that you are using LEVETIRACETAM VIATRIS and or before you have any surgery or emergency treatment.

Tell your doctor if you feel LEVETIRACETAM VIATRIS 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.

If you are pregnant while taking this medicine.

## **Things you should not do**

- Stop taking LEVETIRACETAM VIATRIS, 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 VIATRIS 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.
- Give LEVETIRACETAM VIATRIS to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Take LEVETIRACETAM VIATRIS to treat any other complaints unless your doctor tells you to.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how LEVETIRACETAM VIATRIS affects you.**

As with other antiepileptic medicines, LEVETIRACETAM VIATRIS 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.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

Alcohol combined with taking LEVETIRACETAM VIATRIS may make you drowsy. Your doctor may suggest you avoid alcohol while you are being treated with LEVETIRACETAM VIATRIS.

## **Looking after your medicine**

- Keep your tablets in a cool place where the temperature stays below 25 °C and protect from light.
- Keep your tablets in the pack until it is time to take them. If you take the tablets out of the pack, they will not keep well.

Follow the instructions in the carton on how to take care of your medicine properly.

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 windowsills.

**Keep it where young children cannot reach it.**

## **When to discard your medicine**

If your doctor tells you to stop taking this medicine or the expiry date has passed.

## **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**

<b>Less serious side effects</b>	<b>What to do</b>
<b>Nervous system related:</b> <ul style="list-style-type: none"> <li>• dizziness</li> <li>• forgetfulness</li> </ul>	<b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● loss of concentration</li> </ul> <p><b>Skin related:</b></p> <ul style="list-style-type: none"> <li>● rash</li> <li>● itchy and dry skin</li> </ul> <p><b>Infections related:</b></p> <ul style="list-style-type: none"> <li>● common cold</li> </ul> <p><b>Digestive system related:</b></p> <ul style="list-style-type: none"> <li>● upset stomach</li> <li>● diarrhoea</li> </ul> <p><b>Eye related:</b></p> <ul style="list-style-type: none"> <li>● blurred vision</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>● Muscle pain</li> </ul> <p><b>Other:</b></p> <ul style="list-style-type: none"> <li>● headache</li> <li>● feeling tired, drowsy or sleepy</li> <li>● feeling weak</li> </ul>	

## Serious side effects

Serious side effects	What to do
<p><b>Mood related:</b></p> <ul style="list-style-type: none"><li>• feelings of depression</li><li>• mood changes such as depression, nervousness, aggression, anger, anxiety, confusion, hallucination, irritability.</li><li>• thoughts of harming yourself</li></ul> <p><b>Nervous system related:</b></p> <ul style="list-style-type: none"><li>• more frequent or more severe seizures</li></ul> <p><b>Other:</b></p> <ul style="list-style-type: none"><li>• weight loss</li><li>• a combination of flu-like symptoms, widespread skin rash and/or high temperature.</li></ul> <p><b>Allergic reaction related:</b></p> <ul style="list-style-type: none"><li>• shortness of breath</li><li>• wheezing or difficulty breathing</li></ul>	<p><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></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin.</li> </ul>	

**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 LEVETIRACETAM VIATRIS contains

<b>Active ingredient (main ingredient)</b>	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></ul> Tablet coating contains <ul style="list-style-type: none"><li>• polyvinyl alcohol</li><li>• macrogol</li><li>• talc</li><li>• titanium dioxide</li><li>• iron oxide yellow (500 mg only)</li></ul>
<b>Potential allergens</b>	Not applicable

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

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

## **What LEVETIRACETAM VIATRIS looks like**

LEVETIRACETAM VIATRIS film-coated tablets are blister packed and available in three strengths:

- 250 mg – white to off white tablets, oval biconvex, film coated tablets, debossed ‘L 64’ and breakline on one side and plain on the other side (AUST R 189885)
- 500 mg - yellow coloured tablets, oval biconvex, film coated tablets, debossed ‘L 65’ and breakline on one side and plain on the other side (AUST R 189886)
- 1000 mg - white to off white tablets, oval biconvex, film coated tablets, debossed ‘L 67’ and breakline on one side and plain on the other side (AUST R 189887)

## **Who sponsors LEVETIRACETAM VIATRIS**

Accord Healthcare Pty Ltd  
Level 24, 570 Bourke Street  
Melbourne VIC 3000  
Phone: 1800 134 988

## **Who distributes LEVETIRACETAM VIATRIS**

Alphapharm Pty Ltd trading as Viatris  
Level 1, 30 The Bond  
30-34 Hickson Road  
Millers Point NSW 2000

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

Phone: 1800 274 276

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