

LEVETIRACETAM VIATRIS

Tablets 250 mg/500 mg/1000 mg

levetiracetam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LEVETIRACETAM VIATRIS tablets.

It does not contain all the available information. It does not take the place of talking to your physician or pharmacist.

All drugs have risks and benefits. Your physician has weighed the risks of you taking LEVETIRACETAM VIATRIS tablets against the benefits they expect it will have for you.

If you have any concerns about taking this drug, ask your doctor or pharmacist.

Keep this leaflet with the drug.

You may need to read it again.

What LEVETIRACETAM VIATRIS Tablets are used for

LEVETIRACETAM VIATRIS 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.

LEVETIRACETAM VIATRIS tablets belong to a group of drugs called antiepileptics.

These drugs are thought to work by controlling brain chemicals which

send signals to nerves so that seizures do not happen.

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

Your physician may have prescribed LEVETIRACETAM VIATRIS tablets in addition to your current therapy.

Ask your physician if you have any questions about why this LEVETIRACETAM VIATRIS tablets have been prescribed for you.

There is no evidence that LEVETIRACETAM VIATRIS tablets are addictive.

This drug is available only with a physician's prescription.

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

Before you take LEVETIRACETAM VIATRIS Tablets

When you must not take it

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

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

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

If you are not sure whether you should start taking

LEVETIRACETAM VIATRIS

tablets, talk to your physician or pharmacist.

Before you start to take it

Tell your physician or pharmacist if you have allergies to:

- any other drugs, especially barbiturates (such as phenobarbitone) or any other antiepileptic drugs (such as carbamazepine, lamotrigine or valproate)
- any other substances, such as foods, preservatives or dyes

Tell your physician if you have or have had any medical conditions, especially the following:

- kidney problems

liver problems

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

LEVETIRACETAM VIATRIS 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 physician will outline and weigh up all the risks and benefits of taking LEVETIRACETAM VIATRIS tablets during pregnancy to help decide whether or not you should take it.

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

The active ingredient in LEVETIRACETAM VIATRIS tablets passes into breast milk and there is a possibility that your baby may be affected. Your physician will discuss the risks and benefits of using LEVETIRACETAM VIATRIS tablets if you are breastfeeding.

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

Taking other drugs

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

Some LEVETIRACETAM VIATRIS tablet does not interact with the oral contraceptive pill.

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

Your physician may advise you to use an additional method of contraception if you take LEVETIRACETAM VIATRIS tablets with other antiepileptic drugs.

How to take LEVETIRACETAM VIATRIS Tablets

Follow all directions given to you by your physician carefully.

They may differ from the information contained in this leaflet.

Your physician will tell you how much LEVETIRACETAM VIATRIS 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 drug.

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 physician 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 physician may start you on a low dose of LEVETIRACETAM VIATRIS 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 physician or pharmacist for help.

How to take it

Swallow the LEVETIRACETAM VIATRIS tablet whole with a glass of water.

When to take it

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

Taking LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS tablet before or after food.

If you forget to take it

Contact your physician 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 physician or pharmacist.

If you have trouble remembering to take your drug, ask your pharmacist for some hints.

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 LEVETIRACETAM VIATRIS tablet for as long as your physician tells you to.

LEVETIRACETAM VIATRIS tablet helps control your condition, but does not cure it. Therefore you must take your drug every day, even if you feel well.

Do not stop taking LEVETIRACETAM VIATRIS tablet, or change the dosage, without checking with your physician. Do not let yourself run out of drug over the weekend or on holidays.

Stopping LEVETIRACETAM VIATRIS tablet suddenly may cause unwanted effects or make your condition worse. Your physician will slowly reduce your dose before you can stop taking it completely.

If you take too much (overdose)

Immediately telephone your physician or the Poisons Information Centre (the telephone number in Australia is 131 126 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 LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS Tablets

Things you must do

Tell your physician immediately if you notice an increase in seizures.

Tell your physician immediately if you have symptoms of depression or thoughts of harming yourself.

Tell any other physicians, dentists, and pharmacists who are treating you that you are taking LEVETIRACETAM VIATRIS tablet.

If you are about to be started on any new drug, tell your physician, dentist or pharmacist that you are taking LEVETIRACETAM VIATRIS tablet.

Before you have any surgery or emergency treatment, tell your physician or dentist that you are taking LEVETIRACETAM VIATRIS tablet.

Tell your physician if you feel LEVETIRACETAM VIATRIS tablet is not helping your condition.

Your physician may need to change your drug.

Tell your physician if, for any reason, you have not taken LEVETIRACETAM VIATRIS tablet exactly as prescribed.

Otherwise, your physician may change your treatment unnecessarily.

If you become pregnant while taking LEVETIRACETAM VIATRIS tablet, tell your physician.

Be sure to keep all of your physician's appointments so that your progress can be checked.

Your physician 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 LEVETIRACETAM VIATRIS tablet to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.

Do not take LEVETIRACETAM VIATRIS tablet to treat any other complaints unless your physician tells you to.

Do not stop using it unless your physician tells you to.

Things to be careful of

Be careful driving or operating machinery until you know how LEVETIRACETAM VIATRIS tablet affects you. Children should be careful doing things like riding bicycles or climbing trees.

As with other antiepileptic drugs, LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS tablet.

Combining LEVETIRACETAM VIATRIS tablet and alcohol can make you more drowsy. Your physician may suggest you avoid alcohol while you are being treated with LEVETIRACETAM VIATRIS tablet.

Side effects

Tell your physician or pharmacist as soon as possible if you do not feel well while you are taking LEVETIRACETAM VIATRIS tablet.

LEVETIRACETAM VIATRIS tablet helps most people with epilepsy, but it may have unwanted side effects in a few people. All drugs 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 physician or pharmacist to answer any questions you may have.

If you get any side effects, do not stop taking LEVETIRACETAM VIATRIS tablet without first talking to your physician or pharmacist.

Tell your physician 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

The above list includes the more common side effects of

LEVETIRACETAM VIATRIS tablet.

They are usually mild and short-lived.

Tell your physician as soon as possible if you notice any of the following:

- mood changes such as depression, nervousness, aggression, anger, 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 physician 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 physician if you notice anything else that is making you feel unwell.

Other side effects not listed above may happen in some people.

After using LEVETIRACETAM VIATRIS 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 LEVETIRACETAM VIATRIS tablet or any other drug 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 drugs.

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 drugs.

Disposal

If your physician tells you to stop taking LEVETIRACETAM VIATRIS tablet or expiry date has passed, ask your pharmacist what to do with any drug that is left over.

Product description

What it looks like

LEVETIRACETAM VIATRIS 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.

LEVETIRACETAM VIATRIS Tablets

500 mg – Yellow coloured, oval biconvex, film-coated tablets, debossed

‘L 65’ and breakline on one side and plain on the other side.

LEVETIRACETAM VIATRIS 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.

LEVETIRACETAM VIATRIS Tablets

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

Ingredients

Active ingredient(s):

LEVETIRACETAM VIATRIS Tablets

250 mg – contain 250 mg of Levetiracetam as the active ingredient.

LEVETIRACETAM VIATRIS Tablets

500 mg – contain 500 mg of Levetiracetam as the active ingredient.

LEVETIRACETAM VIATRIS Tablets

1000 mg – contain 1000 mg of Levetiracetam as the active ingredient.

Other ingredients: carmellose sodium, povidone, colloidal anhydrous silica and magnesium stearate.

LEVETIRACETAM VIATRIS 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).

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

Sponsor

Accord Healthcare Pty Ltd. Level 24, 570 Bourke Street

Melbourne, Victoria, 3000 Australia

Distributor

LEVETIRACETAM VIATRIS is distributed in Australia by:

**Alphapharm Pty Ltd trading as
Viatrix**

Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatrix.com.au
Phone: 1800 274 276

This leaflet was prepared in March
2024.

Australian registration numbers:

LEVETIRACETAM VIATRIS

Tablets 250 mg:

AUST R 189885

LEVETIRACETAM VIATRIS

Tablets 500 mg:

AUST R 189886

LEVETIRACETAM VIATRIS

Tablets 1000 mg:

AUST R 189887

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