

LORAZEPAM VIATRIS

Contains the active ingredient lorazepam

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LORAZEPAM VIATRIS.

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

All medicines have benefits and risks. Your doctor has weighed the risks of you taking LORAZEPAM VIATRIS against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, talk to your doctor or pharmacist.

Keep this leaflet with your medicine.

You may need to read it again.

What LORAZEPAM VIATRIS is used for

LORAZEPAM VIATRIS tablets contain the active ingredient lorazepam, which belongs to a group of medicines called

benzodiazepines. They are thought to work by their action on brain chemicals.

LORAZEPAM VIATRIS is used to relieve anxiety. However anxiety or tension associated with the normal stress of everyday life usually does not require treatment with medicines.

It is also used before surgery to help relax you.

In general, benzodiazepines such as LORAZEPAM VIATRIS should be taken for short periods only (for example 2-4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Ask your doctor if you have any questions about why LORAZEPAM VIATRIS has been prescribed for you.

Your doctor may have prescribed it for another purpose.

LORAZEPAM VIATRIS is available only with a doctor's prescription.

Before you use LORAZEPAM VIATRIS

When you must not take it

Do not take LORAZEPAM VIATRIS if:

- you are allergic to lorazepam, any of the ingredients at the end of this leaflet or any other medicine from the benzodiazepine group of medicines
- you have severe and chronic lung disease
- you have sleep apnoea, a condition where you have breathing problems when you sleep
- you are depressed with or without anxiety problems

Lorazepam can increase thoughts of death or suicide.

Do not take LORAZEPAM VIATRIS if the expiry date (Exp.) printed on the pack has passed.

Do not take LORAZEPAM VIATRIS if the packaging is torn or shows signs of tampering.

Do not give this medicine to children unless advised by the child's doctor.

The safety and effectiveness of LORAZEPAM VIATRIS in children under 16 years has not been established.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines,
- any other substances, such as foods, preservatives or dyes.

Tell your doctor or pharmacist if you are pregnant or intend to become pregnant.

Do not take LORAZEPAM VIATRIS if you are pregnant or planning to become pregnant unless you and your doctor have discussed the risks and benefits involved.

LORAZEPAM-VIATRIS may affect the development of newborn babies and cause breathing difficulty, muscle stiffness, a drop in body temperature or yellowing of the skin.

Babies born to mothers who take LORAZEPAM-VIATRIS throughout their pregnancy may be at risk of withdrawal symptoms. The baby may require ventilation at birth.

Tell your doctor if you become pregnant or are breast-feeding.

Do not take LORAZEPAM VIATRIS if you are breast feeding or planning to breast feed unless you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you have any other medical conditions including:

- liver, kidney or lung disease
- blood disorders
- fits or convulsions
- severe muscle weakness known as myasthenia gravis
- low blood pressure
- glaucoma (high pressure in the eye)

- depression, psychosis or schizophrenia.

Tell your doctor if you drink alcohol regularly.

Alcohol may increase the effects of LORAZEPAM VIATRIS.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given LORAZEPAM VIATRIS.

Taking other medicines

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

Some medicines may interfere with LORAZEPAM VIATRIS, or may affect how well it works.

- These include:
- other sleeping tablets, sedatives or tranquillisers
- medicines for depression
- medicines for allergies for example antihistamines or cold tablets
- pain relievers
- muscle relaxants
- medicines to control fits.

These medicines may increase the effects of LORAZEPAM VIATRIS. You may need to take different amounts of your

medicine or you may need to take different medicines. Your doctor will advise you.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

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

How to take LORAZEPAM VIATRIS

How much to take

The dose of LORAZEPAM VIATRIS may be different for each person. Your doctor will decide the right dose for you.

For anxiety, the usual daily dose is 2 to 3 mg administered in divided doses. However the daily dose can range from 1 to 10 mg.

For sleeping problems (insomnia) due to anxiety, a dose of 1 to 2 mg taken at bedtime is usually prescribed.

If you are taking LORAZEPAM VIATRIS before surgery the usual dose is 2 to 4 mg the night before surgery. Another dose of 2 to 4 mg may also be given 1 to 2 hours before surgery.

Elderly people may need a lower dose.

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

How to take it

Swallow the tablets with a glass of water.

It may be taken with or without food.

When to take it

Your doctor will tell you how many times during the day you need to take LORAZEPAM VIATRIS.

How long to take LORAZEPAM VIATRIS for

Do not take LORAZEPAM VIATRIS for longer than your doctor says.

LORAZEPAM VIATRIS is usually used for short periods only (for example 2-4 weeks). Continuous long term use is not recommended unless advised by your doctor. The use of benzodiazepines may lead to dependence on the medicine.

Continue taking LORAZEPAM VIATRIS as long as your doctor recommends it.

If you forget to take LORAZEPAM VIATRIS

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the forgotten dose.

If you have missed more than two doses in a row, speak to your doctor or pharmacist.

If you are unsure about whether to take your next dose, speak to your doctor or pharmacist.

If you are taking LORAZEPAM VIATRIS for insomnia due to anxiety and forget to take LORAZEPAM VIATRIS before you go to bed, do not take any LORAZEPAM VIATRIS if you wake up late in the night or early morning.

Taking LORAZEPAM VIATRIS late at night or early in the morning may make it hard for you to wake in the morning. If you have any questions about this, ask your doctor or pharmacist.

If you take too much LORAZEPAM VIATRIS (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much LORAZEPAM VIATRIS. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too much LORAZEPAM VIATRIS you may feel drowsy, confused, tired, dizzy, have difficulty breathing, feel weak or become unconscious.

While you are using LORAZEPAM VIATRIS

Things you must do

Take LORAZEPAM VIATRIS exactly as your doctor has prescribed.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while you are taking LORAZEPAM VIATRIS, tell your doctor immediately.

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

If you are being treated for anxiety, be sure to discuss with your doctor any problems you may have and how you feel, especially if your anxiety attacks are getting worse or more frequent.

This will help your doctor to determine the best treatment for you.

Visit your doctor regularly.

Your doctor needs to check your progress and see whether you need to keep taking LORAZEPAM VIATRIS.

Always discuss with your doctor any problems or difficulties you have during or after taking LORAZEPAM VIATRIS.

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

Otherwise your doctor may think that it was not effective and change your treatment unnecessarily.

Keep enough LORAZEPAM VIATRIS to last weekends and holidays.

Things you must not do

Do not drive or operate machinery until you know how LORAZEPAM VIATRIS affects you.

This medicine may cause drowsiness or dizziness in some people and therefore may affect alertness.

Make sure you know how you react to LORAZEPAM VIATRIS before you drive a car, operate machinery, or do anything else that could be dangerous if you are drowsy, dizzy or not alert.

Even if you take LORAZEPAM VIATRIS at night, you may still be drowsy or dizzy the next day.

Do not take LORAZEPAM VIATRIS for a longer time than your doctor has prescribed.

LORAZEPAM VIATRIS should be taken for short periods only (for example 2 to 4 weeks), unless advised otherwise by your doctor.

Do not change your dose without first checking with your doctor.

Do not stop taking LORAZEPAM VIATRIS or lower the dose, without first checking with your doctor.

Stopping this medicine suddenly may cause some unwanted withdrawal effects. This is more common in patients that have taken high doses over longer periods of time.

Withdrawal symptoms may include insomnia, anxiety, unusual mood, fast heartbeat, panic attacks, dizziness, lack of normal movement, light sensitivity, increased sound and touch sensitivity, abnormal body sensations (e.g. feels of motion, metallic taste), confusion, hallucinations, vomiting, sweating and loss of short-term memory.

Your doctor will slowly reduce your dose before you can stop taking it completely. This will minimise these unwanted withdrawal symptoms.

Do not suddenly stop taking LORAZEPAM VIATRIS if you suffer from epilepsy.

Stopping this medicine suddenly may make your epilepsy worse.

Do not use this medicine to treat any other complaints unless your doctor says to.

Do not give LORAZEPAM VIATRIS to anyone else, even if their symptoms seem similar to yours.

Things to be careful of

Be careful when drinking alcohol while you are taking this medicine.

If you drink alcohol, symptoms such as dizziness and drowsiness may be worse.

Your doctor may suggest that you avoid alcohol or reduce the amount of alcohol you drink while you are taking LORAZEPAM VIATRIS.

Be careful if you are elderly, unwell or taking other medicines.

Some people may experience side effects such as drowsiness, confusion, dizziness and unsteadiness, which may increase the risk of a fall.

Side effects

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

LORAZEPAM VIATRIS helps most people with anxiety but it may have unwanted side effects in some people.

All medicines may 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.

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

If side effects do happen, they are more likely to happen when you first start taking LORAZEPAM VIATRIS. These side effects may go away during treatment as your body adjusts to the dose.

However, tell your doctor if you notice any of the following and they worry you:

- drowsiness
- dizziness
- sleepiness
- clumsiness or unsteadiness
- weakness
- loss of memory.

These are the more common side effects of LORAZEPAM VIATRIS.

Other less common or rare side effects include:

- skin rashes

- feeling sick or vomiting
- outbursts of anger and increased excitement
- confusion or depression
- headache
- sleep disturbances
- blurred vision
- low blood pressure
- dry mouth
- excessive salivation
- changes in appetite
- nausea.

Tell your doctor if you notice anything else that is making you feel unwell when you are taking, or soon after you have finished taking, LORAZEPAM VIATRIS.

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

Ask your doctor or pharmacist if there is anything you don't understand.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking LORAZEPAM VIATRIS

If you have any queries about any aspect of your medicine, or any questions regarding the information in this leaflet, discuss them with your doctor or pharmacist.

Storage

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

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

Do not store LORAZEPAM VIATRIS or any other medicine in the bathroom or near a sink.

Do not leave LORAZEPAM VIATRIS in the car or on window sills.

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 LORAZEPAM VIATRIS, or your tablets have passed its expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

LORAZEPAM VIATRIS 1 mg:

white, round, flat, beveled, scored tablets, with the inscription “1.0” on one side.

LORAZEPAM VIATRIS 2.5 mg:

white, round, flat, beveled, scored tablets.

Each blister pack contains:

1 mg & 2.5mg – 50 tablets

Ingredients

The active ingredient in LORAZEPAM VIATRIS is lorazepam.

The tablet also contains the following inactive ingredients:

- maize starch
- microcrystalline cellulose

- sodium starch glycollate (Type A)
- lactose monohydrate
- povidone
- crospovidone
- magnesium stearate
- polacrillin potassium.

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

Sponsor

Southern Cross Pharma Pty Ltd

Suite 2, Level 2

19-23 Prospect Street

Box Hill, Vic, 3128

Distributor

LORAZEPAM VIATRIS is distributed in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

Australian registration numbers:

LORAZEPAM VIATRIS 1 mg

AUST R 304312

LORAZEPAM VIATRIS 2.5 mg

AUST R 304313

Date of preparation:

October 2024.