LORAZEPAM VIATRIS

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking LORAZEPAM VIATRIS?

LORAZEPAM VIATRIS contains the active ingredient lorazepam. LORAZEPAM VIATRIS is used to relieve anxiety or before surgery to help relax you. For more information, see Section 1. Why am I taking LORAZEPAM VIATRIS? in the full CMI.

2. What should I know before I take LORAZEPAM VIATRIS?

Do not take if you have ever had an allergic reaction to LORAZEPAM VIATRIS 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 take LORAZEPAM VIATRIS? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LORAZEPAM 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 take LORAZEPAM VIATRIS?

- Swallow the tablets with a glass of water with or without food.
- Your doctor will tell you how many times during the day you need to take LORAZEPAM VIATRIS and at what times.

More instructions can be found in Section <u>4. How do I take LORAZEPAM VIATRIS?</u> in the full CMI.

5. What should I know while taking LORAZEPAM VIATRIS?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are taking LORAZEPAM VIATRIS.
- If you become pregnant while you are taking

LORAZEPAM VIATRIS, tell your doctor immediately.

- Take LORAZEPAM VIATRIS exactly as your doctor has prescribed and tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LORAZEPAM VIATRIS.
- Visit your doctor regularly and always discuss any problems or difficulties you have during or after taking LORAZEPAM VIATRIS.

Things you should not do

- Do not take LORAZEPAM VIATRIS for longer than your doctor says.
- Do not change your dose of LORAZEPAM VIATRIS or stop taking it without first checking with your doctor.
- Do not suddenly stop taking LORAZEPAM VIATRIS if you suffer from epilepsy.

Driving or using machines	 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. Even if you take LORAZEPAM VIATRIS at night, you may still be drowsy or dizzy the next day.
Drinking alcohol	 Alcohol may increase the effects of LORAZEPAM VIATRIS.
Looking after your medicine	 Keep your tablets in the pack until it is time to take them. Keep your tablets in a cool dry place where the temperature stays below 25°C.

For more information, see Section <u>5. What should I know while taking LORAZEPAM VIATRIS?</u> in the full CMI.

6. Are there any side effects?

Common side effects include drowsiness, dizziness, sleepiness, clumsiness or unsteadiness, weakness and loss of memory.

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 and nausea. These side effects may be serious.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

LORAZEPAM VIATRIS

Active ingredient(s): lorazepam

Consumer Medicine Information (CMI)

This leaflet provides important information about taking LORAZEPAM 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 taking LORAZEPAM VIATRIS.

Where to find information in this leaflet:

- 1. Why am I taking LORAZEPAM VIATRIS?
- 2. What should I know before I take LORAZEPAM VIATRIS?
- 3. What if I am taking other medicines?
- 4. How do I take LORAZEPAM VIATRIS?
- 5. What should I know while taking LORAZEPAM VIATRIS?
- 6. Are there any side effects?
- 7. Product details

1. Why am I taking LORAZEPAM VIATRIS?

LORAZEPAM VIATRIS contains the active ingredient lorazepam. LORAZEPAM VIATRIS 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.

LORAZEPAM VIATRIS 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.

2. What should I know before I take LORAZEPAM VIATRIS?

Warnings

Do not take LORAZEPAM VIATRIS if:

- you are allergic to lorazepam, or any of the ingredients listed 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.

Check with your doctor if you:

- 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.

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.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

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.

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.

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.

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.

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

4. How do I 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.

When to take LORAZEPAM VIATRIS

 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.
- LORAZPEAM 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.

How to take LORAZEPAM VIATRIS

- Swallow the tablets with a glass of water.
- It may be taken with or without food.

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

If you think that you have taken too much LORAZEPAM 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.

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

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

5. What should I know while taking LORAZEPAM VIATRIS?

Things you should 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.

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 should not do

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.

Driving or taking machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

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.

Use in the Elderly

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.

Looking after your medicine

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.

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 window sills.

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

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not take 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.

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.

Less serious/common side effects

Less serious/common side effects	What to do
 drowsiness dizziness sleepiness clumsiness or unsteadiness 	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious/common side effects	What to do
weakness	
loss of memory	

Less common/rare side effects

Less common/rare side effects	What to do
 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 	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.

These side effects may be serious.

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. 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 LORAZEPAM VIATRIS contains

Active ingredient	lorazepam
(main ingredient)	
Other ingredients	maize starch
(inactive ingredients)	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.

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

What LORAZEPAM VIATRIS looks like

LORAZEPAM VIATRIS 1 mg:

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

(AUST R 304312)

LORAZEPAM VIATRIS 2.5 mg:

white, round, flat, beveled, scored tablets.

(AUST R 304313)

Each blister pack contains 50 tablets

Who distributes LORAZEPAM VIATRIS

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

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