

Package leaflet: Information for the user

Lorazepam 1 mg Tablets Lorazepam 2.5 mg Tablets

Lorazepam

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lorazepam is and what it is used for
2. What you need to know before you take Lorazepam
3. How to take Lorazepam
4. Possible side effects
5. How to store Lorazepam
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1. What Lorazepam is and what it is used for

The name of your medicine is Lorazepam Tablets, called Lorazepam in the rest of the leaflet. Lorazepam is a member of a group of medicines called benzodiazepines. It can help to relieve anxiety. Lorazepam is prescribed as short-term therapy for anxiety (2-4 weeks), or sleeping difficulties due to anxiety. It may also be used as a sedative before surgery or operative dental treatment.

Lorazepam is not to be used for longer than 4 weeks, to treat mild or moderate anxiety in adults or for anxiety/insomnia in children.

2. What you need to know before you take Lorazepam

Do not take Lorazepam

- If you are allergic to benzodiazepines or any of the other ingredients of this medicine (listed in section 6).
- If you have severe breathing or chest problems
- If you have myasthenia gravis (very weak or tired muscles)
- If you have serious liver problems

- If you suffer from sleep apnoea (breathing problems when you are asleep)
- If you are planning a pregnancy or are pregnant

If you are breast-feeding, since the drug may pass into breast milk.

If you have been only prescribed Lorazepam for anxiety and no other medications, please consult with your doctor whether other medications should also be prescribed.

Warnings and precautions

Talk to your doctor before taking Lorazepam:

- If you abuse or have in the past abused drugs or alcohol.
- If you have a personality disorder. If so, you have a greater chance of becoming dependent on Lorazepam.
- If you have any kidney or liver problems
- If you have suffered from depression before, since it could re-occur during treatment with lorazepam
- If you are suffering from depression, since Lorazepam may increase any suicidal feelings which you may have.
- If you suffer from breathing problems
- If you are suffering from an eye problem called glaucoma e.g. high pressure within the eye.

Lorazepam may cause muscle relaxation and caution is advised as you may be at a greater risk of falling (see section 4).

Other medicines and Lorazepam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those which have not been prescribed by a doctor, since they may affect the way Lorazepam work. Lorazepam may also affect the way other drugs work. In particular, you should tell your doctor if you are taking:

- Any other sedative (e.g. barbiturates or antihistamines), anti-anxiety drugs
- Antidepressants
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- Strong pain killers (e.g. methadone)
- Drugs for epilepsy (e.g. phenobarbital or valproate)
- Antihistamine or
- Drugs for mood or mental disorders (e.g. chlorpromazine, loxapine or clozapine).
- Drugs for cataplexy
- Treating HIV
- To treat delusions or hallucinations
- To help with indigestion (e.g. omeprazole)
- Muscle relaxants (e.g. baclofen and tizanidine)
- Drugs for addiction treatment (e.g. lofexidine and disulfiram)
- TB drugs such as isoniazid
- Antibiotics such as erythromycin
- Drugs to treat high blood pressure
- Parkinson's disease drugs e.g. levodopa.

- Oestrogen-containing contraceptives and
- Drugs for asthma(theophylline)
- Anti-fungal medicines (Itraconazole, ketoconazole, fluconazole, voriconazole), diuretics and nabilone

The dose of these drugs may need to be reduced before you can take Lorazepam.

Concomitant use of this product and opioids (strong pain killers, medicines for substitution therapy and some cough medicines) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.

However if your doctor does prescribe this product together with opioids the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all opioid medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Lorazepam with food, drink and alcohol

Do not drink any alcohol while taking Lorazepam.

Grapefruit juice and drinks containing caffeine should be avoided as they can affect the way that Lorazepam work.

Pregnancy and breast-feeding

Pregnancy

Do not take this medicine if you are pregnant, or might become pregnant, without consulting your doctor. Benzodiazepines, includinglorazepam may cause damage to the foetus if taken during early pregnancy.

If you take this medicine during late pregnancy or during labour, your baby, when born, may be less active than other babies, have low body temperature ,be floppy, or have breathing or feeding difficulties for a while. Your baby's response to the cold might be temporarily impaired. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms after birth.

Breast-feeding

Do not take this medicine if you are breast-feeding, since the drug may pass into breast milk, and cause the baby to be less active and unable to suckle.

Driving and using machines

Lorazepam may make you feel dizzy, sleepy or forgetful during the day, or may affect your concentration. This may affect your performance at skilled tasks such as driving

machinery or operating machinery by affecting your vision or muscle function. You should not take part in any other activities where this could put yourself or others at risk.

You should avoid alcohol while you are taking Lorazepam, since this may make you very drowsy and seriously affect your ability to drive or use machines.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:

The medicine has been prescribed to treat a medical or dental problem and

- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely.

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Lorazepam contains lactose and sodium

Lorazepam contain lactose as lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Lorazepam contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Lorazepam

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Lorazepam Tablets should be swallowed with water.

Adults (and children over 13 years of age):

- **Anxiety:** 1 to 4mg daily in divided doses. Your doctor will tell you how often to take your tablets.
- **Sleeping Problems:** 1 to 2mg before going to sleep. You should make sure that you will be able to sleep for 7 to 8 hours before taking your tablets.
- **Before Surgery:** 2 to 3mg the night before your operation and 2 to 4mg 1 or 2 hours before your operation.

Children (between 5 and 13 years of age)

- **Before Surgery:** The dose is usually between 0.5 and 2.5mg (depending on your child's weight) at least 1 hour before your child's operation.
- Lorazepam is not recommended for the treatment of anxiety or sleeping problems in children. Nor is it recommended for children below 5 years of age.

Elderly or patients with liver or kidney problems:

- Older patients may be given lower doses. They may respond to half the usual adult dose or less. Lorazepam is usually prescribed for short courses of treatment, lasting from a few days to 4 weeks including a dose reduction at the end. This reduces the risk of becoming dependent on Lorazepam, or suffering unpleasant effects when you stop taking them. (See 'If you stop taking Lorazepam' section).

The beneficial effect of Lorazepam may be less apparent after several weeks of use. If you are given lorazepam for more than 4 weeks, your doctor might want to take blood samples occasionally to check your blood and liver, since drugs like Lorazepam have occasionally affected blood and liver function.

If you take more Lorazepam than you should

If anyone has taken an overdose of Lorazepam Tablets (that is more than the doctor has prescribed), seek medical help immediately, either by calling your doctor, or going to the nearest casualty department. Always take the labelled medicine container with you, even if there are no tablets left.

If you forget to take Lorazepam

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

If you forget to take a tablet for anxiety, you should take it as soon as you remember if it is less than 3 hours since your usual time. If more than 3 hours has passed from when you usually take your tablet, just take your next tablet when it is due.

If you forget to take a tablet for sleeping problems, only take it if you will be able to sleep for 7 to 8 hours afterwards.

If you stop taking Lorazepam

- After you have finished your prescribed treatment with Lorazepam, your doctor will decide whether you need further treatment.
- The number of Lorazepam tablets, and how often you take them, should always be reduced slowly before stopping them. This allows your body get used to being without your tablets, and reduces the risk of unpleasant effects when you stop taking them. Your doctor will tell you how to do this.
- On stopping Lorazepam, you may experience symptoms such as headache, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Your original sleeplessness may also return. If you suffer from any of these symptoms, ask your doctor for advice.
- Do not stop taking your tablets suddenly. This could lead to more serious symptoms such as loss of sense of reality, feeling unreal or detached from life, and unable to feel emotion. Some patients have also experienced numbness or tingling of the arms or legs, tinnitus (ringing sounds in the ears), oversensitivity to light, sound and touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormally fast heartbeats, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very warm, convulsions (sudden uncontrolled shaking or jerking of the body).

- Patients taking anti-depressants and patients with seizure disorders may be more likely to experience convulsions.

If you suffer from any of these symptoms, ask your doctor for advice immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. If you experience any of the following serious unwanted effects, you should tell your doctor immediately (these effects are more likely to occur in children and elderly patients):

- Restlessness, agitation, irritability, aggressiveness, violent anger, sleeping difficulties, nightmare, hallucinations, personality changes, sexual arousal, abnormal behaviour or false beliefs.
- Unexplained bleeding and/or bruising; increased risk of infections e.g. frequent sore throats, mouth ulcers, weakness and pale skin as these are symptoms of blood dyscrasia
- Impaired consciousness (e.g. reduced alertness, confusion, disorientation, fainting) as this may ultimately lead to coma
- Thoughts of harming or killing yourself, becoming dependant on Lorazepam.
- Severe allergic reactions e.g. difficulty in breathing, swelling of the lips, mouth, tongue, throat, hands, feet and/or severe faintness or dizziness.
- Jaundice e.g. yellowing of the skin, eyes, nose, mouth, pale coloured stools (faeces) and dark coloured urine.

Other side effects

Very common (may affect more than 1 in 10 people):

- Daytime drowsiness

Common (may affect up to 1 in 10 people):

- Dizziness
- Poor muscle control
- Muscle weakness
- Fatigue

Rare (may affect up to 1 in 1,000 people):

- Depression,
- Numbed emotions
- Difficulty controlling urges and impulses to speak, act or show emotions
- A feeling of well-being for no reason
- Appetite changes
- Sleep problem
- Changes in sex drive
- Decreased orgasm
- Headache
- Slurred speech
- Memory loss or forgetfulness

- Problems with vision including double vision or blurred vision
- Worsening of sleep apnoea (e.g. loud snoring, restlessness and choking/gasping during the night)
- Breathing difficulties
- Stomach upset
- Nausea
- Constipation
- Changes in the amount of saliva in the mouth
- Skin problems such as rashes and inflammation
- Erectile dysfunction
- Blood or liver changes
- Low blood pressure or low body temperature.

Very rare (may affect up to 1 in 10,000 people):

- Trembling or shaking.
- Low blood sodium

Not known (frequency cannot be estimated from the available data):

- Increased risk of falling

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly.

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 Earlsfort Terrace
 IRL - Dublin 2
 Tel: +353 1 6764971
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 Website: www.hpra.ie
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By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lorazepam

Keep this medicine out of the sight and reach of children.

Store below 25°C. Store in the original container to protect from light.

Do not use this medicine after the expiry date which is stated on the carton and the blister after EXP. The expiry date refers to the last day of that month.

Return any unused tablets to your pharmacist. Only keep them if your doctor tells you to.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lorazepam contains

- The active substance is lorazepam, either 1 mg or 2.5 mg in a tablet.
- The other ingredients are: lactose monohydrate; povidone (K30); crospovidone, type A; maize starch; microcrystalline cellulose; sodium starch glycolate; magnesium stearate and polacrillin potassium.

What Lorazepam looks like and contents of the pack

Lorazepam 1 mg: white, round, flat, bevelled, scored tablets, inscribed 1.0.

Lorazepam 2.5 mg: white, round, flat, bevelled, scored tablets.

Blister packs containing 10, 14, 15, 20, 28, 30, 50, 60, 90, 100 or (only available to pharmacies or hospitals) 500 tablets are available.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Aspire Pharma (Malta) Limited
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