

# Package leaflet: Information for the user Lorazepam 1mg/ml Oral Solution

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.

The name of your medicine is Lorazepam 1mg/ml Oral Solution but it will be referred to as 'Lorazepam' throughout this leaflet.



## 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
6. Contents of the pack and other information

### 1. What Lorazepam is and what it is used for

Lorazepam is a member of a group of medicines called benzodiazepines. It can help to relieve severe anxiety. Lorazepam is prescribed as short-term therapy for anxiety (2-4 weeks), or sleeping difficulties due to anxiety that significantly affects normal daily life. 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 or to treat mild or moderate anxiety in adults.

You must talk to a doctor if you do not feel better or if you feel worse.

### 2. What you need to know before you take Lorazepam



#### Do not take Lorazepam:

- ▶ if you have severe breathing or chest problems
- ▶ if you are allergic to lorazepam, other benzodiazepines or any of the other ingredients of this medicine (listed in section 6)
- ▶ 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 have been only prescribed Lorazepam for anxiety and no other medications, please consult with your doctor whether other medications should also be prescribed.

Some elderly patients may feel dizzy after taking Lorazepam and may be in danger of falling.

#### Warnings and precautions

Talk to your doctor or pharmacist before taking Lorazepam:

- ▶ if you are pregnant or trying to become pregnant
- ▶ 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 are elderly or debilitated (weak)
- ▶ 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 have a history of psychotic illness
- ▶ if you have a history of convulsions/seizures
- ▶ 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 (including at hospital if you enter for treatment) 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 works.

Lorazepam may also affect the way other medicines work.

In particular, you should tell your doctor if you are taking:

- ▶ any other sedative (e.g. barbiturates)
- ▶ anti-anxiety drugs
- ▶ anti-depressants
- ▶ probenecid (a drug to treat gout)
- ▶ strong pain killers (e.g. opioids - keep the dosages and duration of the medicine to a minimum as recommended by your doctor). Taking Lorazepam with these pain killers may make you more sleepy and in rare cases can cause breathing difficulty and death.
- ▶ drugs for epilepsy (e.g. phenobarbital or sodium valproate)
- ▶ antihistamines
- ▶ anti-psychotic drugs for mood or mental disorders (e.g. chlorpromazine, loxapine or clozapine)
- ▶ anaesthetics
- ▶ drugs for cataplexy (sudden and temporary muscular weakness triggered by strong emotions such as laughter, anger and surprise)
- ▶ drugs for treating HIV
- ▶ drugs to treat delusions or hallucinations
- ▶ drugs to help with indigestion (e.g. omeprazole)
- ▶ muscle relaxants (e.g. baclofen and tizanidine)
- ▶ drugs for addiction treatment (e.g. methadone, lofexidine and disulfiram)
- ▶ drugs to treat tuberculosis (e.g. isoniazid and rifampicin)
- ▶ antibiotics such as erythromycin
- ▶ drugs to treat high blood pressure
- ▶ drugs to treat Parkinson's disease e.g. levodopa
- ▶ oestrogen-containing contraceptives
- ▶ drugs for asthma (theophylline, aminophylline)

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

Concomitant use of lorazepam 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 lorazepam 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

Grapefruit juice and drinks containing caffeine should be avoided as they can affect the way that Lorazepam works. Do not drink alcohol while you are taking Lorazepam.

#### Tolerance and dependence

Tolerance to benzodiazepines may occur. Therefore the beneficial effect of lorazepam may be less apparent after several weeks of use.

Lorazepam may have abuse potential, especially in patients with a history of drug and/or alcohol abuse.

Dependence is unlikely to occur but the risk increases with higher doses and longer-term use and is further increased in patients with a history of alcoholism, drug abuse or in patients with personality disorders. Therefore use in individuals with a history of alcoholism or drug abuse should be avoided.

Dependence may lead to withdrawal symptoms, especially if treatment is discontinued abruptly. Therefore, the drug should always be discontinued gradually.

Dependence on benzodiazepines may occur following prolonged treatment.

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 liver function.

Dependence on benzodiazepines may occur following prolonged treatment. Therefore 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 it. (See section 3 'If you stop taking lorazepam', below).

Increases in the dosage of lorazepam should be made gradually to help avoid adverse effects. The evening dose should be increased before the daytime doses.



#### Pregnancy, breast-feeding and fertility

- ▶ If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
- ▶ Do not take this medicine if you are pregnant, or might become pregnant, without consulting your doctor. Benzodiazepines, including lorazepam, 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 a 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.
- ▶ 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; unless the expected benefit to the mother outweighs the potential risk to the infant.

#### 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 feel 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 1mg/ml Oral Solution contains:

This medicine contains 20.21mg ethanol (alcohol) per ml. The amount in each ml of this medicine is equivalent to less than 1ml beer or 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

### 3. How to take Lorazepam

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

The recommended dose

#### Adults

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

#### Elderly patients

Elderly and debilitated (weak) patients may be given lower doses. They may respond to half the usual adult dose or less. However, this lower dose may be adjusted if needed.

#### Patients with Renal or Hepatic Impairment

Lower doses may be sufficient in patients with impaired renal function or mild to moderate hepatic insufficiency. Use in patients with severe hepatic insufficiency is contraindicated.

#### Lorazepam is not recommended for use in children.

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 the medicine (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

#### Method of administration:

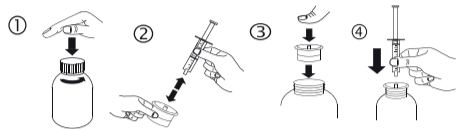
This medicinal product contains medium chain triglycerides which reacts with polystyrene materials and makes it brittle upon contact. Do not use polystyrene dosing devices for measuring the dose.

Use the measuring syringe provided in the pack to deliver the required dose orally.

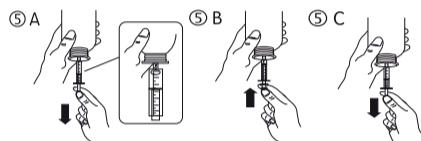
The required dose should be drawn from the container into the graduated syringe provided using the syringe adaptor (see detailed instructions below). The syringe should be held in the mouth of the patient, and the contents of the syringe should then be ejected into the mouth and swallowed.

#### Instructions for the use of syringe:

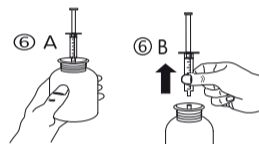
- Open the bottle: press the cap and turn it anticlockwise (figure 1).
- Separate the adaptor from the syringe (figure 2). Insert the adaptor into the bottle neck (figure 3). Ensure it is properly fixed. Take the syringe and put it in the adaptor opening (figure 4).



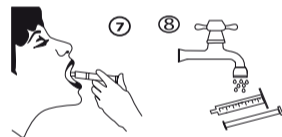
- Turn the bottle upside down. Fill the syringe with a small amount of solution by pulling the piston down (figure 5A), then push the piston upwards in order to remove any possible bubble (figure 5B). Pull the piston down to the graduation mark corresponding to the quantity in millilitres (ml) prescribed by your doctor (figure 5C).



- Turn the bottle the right way up (figure 6A). Remove the syringe from the adaptor (figure 6B).



- Empty the contents of the syringe into the patient's mouth by pushing the piston to the bottom of the syringe (figure 7). The contents of the syringe should be emptied into the side cheek of the patient's mouth to avoid a choking hazard. Leave the syringe adaptor in place after first use. Close the bottle with the plastic screw cap. Wash the syringe with water (figure 8).



#### If you take more Lorazepam than you should

If anyone has taken an overdose of Lorazepam (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 pack with you, even if no medicine is left.

#### If you forget to take Lorazepam

- If you forget to take your medicine 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 medicine, just take your next dose when it is due.
- Do not take a double dose to make up for a forgotten dose.
- If you forget to take your medicine 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 if you need further treatment.
- The amount of Lorazepam and how often you take your medicine should always be reduced slowly before stopping it. This allows your body to get used to being without your medicine, and reduces the risk of unpleasant effects when you stop taking the medicine. Your doctor will tell you how to do this.
- On stopping lorazepam, you may experience withdrawal symptoms such as headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion, irritability, dizziness, nausea, diarrhoea, loss of appetite, agitation, shaking, stomach pain, changes in heart rate, short-term memory loss and high body temperature.
- Your original sleeplessness may also return. If you suffer from any of these symptoms, ask your doctor for advice.
- Do not stop taking the medicine suddenly. This could lead to more serious symptoms such as loss of the 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 have any further questions on the use of this medicine, ask your doctor or pharmacist.

#### 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 elderly patients):

- Severe allergic reactions can occur with benzodiazepine use, even after the first dose. Symptoms include swelling of the tongue or throat, shortness of breath, throat closing, nausea or vomiting. In such cases, immediate medical attention should be sought.
- Benzodiazepines, including lorazepam, may lead to potentially fatal breathing problems.
- Restlessness, agitation, irritability, aggressiveness, violent anger, sleeping difficulties, nightmares, 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 dependent 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  
Drowsiness, fatigue, sedation

Common: may affect up to 1 in 10 people

Dizziness, muscle weakness, Asthenia (loss of strength), Ataxia (poor muscle control), Confusion, Depression, unmasking of depression (revealing signs of depression that were previously hidden)

Uncommon: may affect up to 1 in 100 people

Nausea, Change in libido, Impotence, Decreased orgasm

Not known: frequency cannot be estimated from the available data

Increased sensitivity to light, sound and touch; Convulsions/fits, constipation, yellowing of the skin and eyes, Shaking, Problems with vision (double and blurred vision), Slurred speech, Headache, Memory loss, Heightened emotions, Coma, Impaired attention/concentration, Loss of inhibitions, Thoughts or attempts of suicide, Increase in specific liver enzymes (bilirubin, liver transaminases and alkaline phosphatase), Anxiety, excitation, hostility, aggression, sexual arousal, balance disorder, Difficulty breathing, Difficulty breathing when you are asleep, Worsening of lung disease, Allergic skin reactions (e.g. rash, swelling), Alopecia (loss of hair from the head or body), Hypersensitivity reactions, Angioedema (swelling of the face, hands and feet), SIADH - syndrome of inappropriate antidiuretic hormone hypersecretion (a condition in which the body produces too much antidiuretic hormone (ADH). Increased ADH may cause too much water to remain inside your body.), Hyponatremia (low level of sodium in the blood which can cause tiredness and confusion, muscle twitching, fits and coma), Hypothermia, Lowering of blood pressure, Thrombocytopenia (unexplained bruising, nosebleeds and/or bleeding gums), agranulocytosis (severe infection), pancytopenia (bleeding, bruising easily, fatigue, shortness of breath, and weakness), Vertigo, Problems sleeping.

The following side effects may be more likely to occur in elderly patients:

- Restlessness
- Agitation
- Irritability
- Aggressiveness
- Violent anger
- Nightmares
- Hallucinations
- Personality changes
- Abnormal behaviour
- False beliefs

If any of the side-effects get serious, or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.

#### Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via the Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. 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.
- Do not use this medicine after the expiry date which is stated on the carton and bottle label after EXP. The expiry date refers to the last day of that month.
- Store and transport refrigerated (2°C - 8°C).
- For 60ml pack size: Discard 30 days after first opening.
- For 150ml pack size: Discard 90 days after first opening.
- Keep the bottle in the outer carton in order to protect from light.
- 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.

Each ml of oral solution contains 1mg lorazepam.

The other ingredients are ethanol (alcohol) and medium chain triglycerides.

##### What Lorazepam looks like and contents of the pack

Lorazepam is a clear, colourless to pale yellow colour oral solution supplied in an amber glass bottle, holding 60ml or 150ml of solution, with tamper evident child resistant plastic cap. The pack also contains a 1ml oral syringe and a bottle/syringe adaptor.

Not all pack sizes may be marketed.

##### Marketing Authorisation Holder and Manufacturer:

SyriMed,  
Unit 4, Bradfield Road,  
Ruislip, Middlesex,  
HA4 0NU, UK.

**POM**

**If this leaflet is hard to see or read, please call +44 (0) 208 515 3700 for help.**

**This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:**

**UK (NI):** Lorazepam 1mg/ml Oral Solution  
**MT:** Lorazepam Thame 1mg/ml Oral Solution

This leaflet was last revised in 07/2023.

