• 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 or nurse. This includes any possible side effects not listed in this leaflet.
• This medicine should be used for as short a time as possible and should not be used for more than four weeks. If used for too long without a break, there is a risk of becoming dependent or of having problems when you stop taking it.

In this leaflet:
1. What Lorazepam is and what is it used for?
2. What you need to know before you take Lorazepam
3. How to take Lorazepam Tablets
4. Possible side effects
5. How to store Lorazepam Tablets
6. Contents of the pack and other information

1. What Lorazepam is and what is it used for?
• Lorazepam belongs to a group of medicines called benzodiazepines.
• Lorazepam tablets are used as a short-term therapy for severe anxiety or sleeping difficulties due to anxiety.
• It may also be used as a sedative before general surgery or pre-operative dental treatment.
• When taking this medicine there is a risk of dependence (a need to keep taking the medicine) the risk increases with the dose and length of treatment period. The risk is greater if you have ever had a history of alcohol or drug abuse.

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)
  • have severe breathing or chest problems
  • have ‘myasthenia gravis’ (very weak or tired muscles)
  • have serious liver problems
  • suffer from ‘sleep apnoea’ (breathing problems when you are asleep)
  • have a history of persistently abusing alcohol and/or drugs
  • are pregnant or trying to become pregnant
  • are breast feeding
  • are taking antipsychotics, antidepressants, hypnotics, sedative or antihistamines as these medicines may interact with Lorazepam.
◆ Warnings and precautions
Talk to your doctor or pharmacist before taking these tablets if you:
• have kidney or liver problems
• are suffering from psychiatric illness or a personality disorder
• have suffered or are suffering from depression as it could re-occur during treatment with Lorazepam and if you have suicidal feelings, these may increase
• suffer from an eye problem called glaucoma
• suffer from breathing problem
• are elderly, as you may be more likely to fall
• are taking any other medicine, including those which have not been prescribed by a doctor, as they may affect the way Lorazepam works
• suffer from a condition called ‘porphyria’ (inherited metabolic disorder).
◆ Taking other medicines
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially if you are already taking:
• sedative drugs (e.g. barbiturates)
• analgesics, anti-anxiety drugs, anti-depressants
• strong painkillers (e.g. tramadol, codeine, morphine, methadone)
• sodium oxybate (used to treat narcolepsy)
• zidovudine (used in HIV treatment)
• antiepileptic drugs (e.g. phenobarbital or valproate)
• antihistamines for allergies (e.g. cetirizine, loratadine)
• drugs to treat mood or mental disorders, delusions or hallucinations (e.g. chlorpromazine, clozapine, haloperidol, loxapine)
• muscle relaxants (e.g. baclofen or tizanidine)
• cisapride, omeprazole, esomeprazole (drugs to help treat indigestion)
• drugs to treat high blood pressure, antacids
• drugs to treat parkinson’s disease (e.g. levodopa)
• antifungal drugs such as ketoconazole
• antibiotics (e.g. erythromycin, rifampicin, isoniazid)
• drugs for addiction treatment (e.g. lofexidine, disulfiram)
• oestrogen-containing contraceptives
• drugs for asthma (theophylline/aminophylline).
• medicine for gout called probenecid
• medicine called scopolamine that may be used for gut problems or before an operation.
The dose of these drugs may need to be reduced before you can take Lorazepam.
◆ Using Lorazepam with food, drink and alcohol
• Drinks containing caffeine and grapefruit juice should be avoided while taking these tablets.
• No alcohol should be consumed during treatment with benzodiazepines.
Talk to a pharmacist or your doctor before taking this medicine if you are taking alcohol (see driving information).
• If you take your whole dose in the evening, it should not be taken until four hours after food otherwise you may feel hungover the next day.
◆ Pregnancy and breast-feeding
Do not take this medicine if you are pregnant or breast feeding, think you may be pregnant or are planning to have a baby. Lorazepam may cause damage to the unborn baby if taken during pregnancy. If your doctor has decided that you should receive 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 and feeding difficulties for a while. If this medicine is taken regularly in late pregnancy, your baby may develop withdrawal symptoms after birth. Lorazepam may pass into the breast milk. Therefore it should not be taken while breast feeding, unless the expected benefit outweighs the potential risk for the baby. Your baby may otherwise suffer from sedation and difficulties suckling. In this case, monitoring of the baby is recommended.
◆ Driving and using machines
Lorazepam can cause sedation, impaired concentration, blurred vision, drowsiness, or amnesia which may adversely affect ability to perform skilled tasks such as driving or operating machinery. 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:
  o The medicine has been prescribed to treat a medical or dental problem
  o You have taken it according to the instructions given by the pharmacist or in the information provided with the medicine and
  o 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 tablet contains lactose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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.
◆ Dosage-The dosage of Lorazepam should be adjusted according to the needs of the patient and the minimum dose to control symptoms should be used.

◆ Adults
Anxiety: 1 to 4mg daily in divided doses. Your doctor will tell you how often to take your tablets.
Sleeping Problems: Initially 1mg before retiring to sleep then a usual dose of 1 to 2mg before going to sleep.
Before Surgery: 2 to 3mg the night before your operation and 2 to 4mg 1 or 2 hours before your operation.
• 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.

• How to take

◆ Swallow the tablet with water.

◆ Duration of use

Lorazepam should be used as a short-term therapy for the treatment of severe anxiety or insomnia. Treatment should not normally be continued beyond 4 weeks.

◆ Treatment should if possible be intermittent; the lowest dose to control symptoms should be used.

◆ Long term chronic use is not recommended.

◆ Treatment should always be reduced gradually.

If you take more Lorazepam than you should If you or anyone else has taken too many tablets, contact your doctor or hospital immediately. Bring any remaining tablets with you to show the doctor. Signs of mild overdose include drowsiness, mental confusion, and lethargy; in more serious cases, difficulty speaking, slurred speech, clumsiness or unsteadiness, low muscle tone, dizziness and loss of balance and co-ordination may occur.

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 have passed, then just continue taking your next dose; do not try to catch up by doubling up the dosage. If you are being treated for sleeping problems only take the tablet if you have sufficient sleeping time.

If you stop taking Lorazepam
The number of lorazepam tablets, and how often you take them, should always be reduced slowly before you stop taking them altogether. This lets your body get used to being without lorazepam, and lessens the chances of unpleasant effects when you stop taking them. Your doctor will tell you how to do this.

If you stop taking the tablets suddenly you may experience depression, nervousness, difficulty in sleeping, irritability, sweating, upset stomach, or the symptoms you are being treated for can come back worse than before.

You may also experience mood changes, anxiety, restlessness and changes in sleep patterns. These effects may occur even after taking low doses for a short period of time.

If you stop taking these tablets suddenly after being treated with high doses, you may experience confusion, hallucinations, shaking, faster heartbeat or fits (see section 4). Withdrawal may also cause unusual behaviour including aggressive outbursts, excitement or depression with suicidal thoughts or actions. This medicine should not be stopped suddenly; keep taking it until your doctor tells you how to reduce the dose slowly.

If you have any further questions on the use of this product, 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 side effects, tell your doctor immediately:

• severe allergic reactions like difficulty in breathing, swelling of the lips, mouth, tongue, throat, hands, feet and/or severe faintness or dizziness, sensitivity to light

• changes in your mental state such as: restlessness, agitation, irritability, aggressiveness, violent anger, sleeping difficulties, nightmares, hallucinations, personality changes, abnormal behaviour with suicidal tendency

• unexplained bleeding and/or bruising; increased risk of infections like frequent sore throats, mouth ulcers, weakness and pale skin

• yellowing of the skin, eye, nose, and mouth, pale coloured stools and dark coloured urine

◆ Other side effects:

• Very common (may affect more than 1 in 10 people): fatigue, daytime drowsiness, sedative effect.

• Common (may affect up to 1 in 10 people): dizziness, muscle weakness, poor muscle control, loss of strength, confusion, depression.

• Uncommon (may affect up to 1 in 100 people): change in sex drive

• Rare (may affect up to 1 in 1,000 people): nausea, numbness, change in appetite, stomach upset, headache, reduced alertness, problems with vision, double vision, memory loss or forgetfulness, ringing, buzzing, loss of sensation, low blood pressure, low blood sodium levels, impotence, skin problems.

• Very rare (may affect up to 1 in 10,000 people): tremor, reduction in blood cells and decrease in body temperature.

The following side effects have been reported with lorazepam, but the frequency cannot be estimated from the available data:

• Allergic skin reactions such as reddening, rash, hair loss

• Loss of short term memory

• Muscle spasms, difficulty in opening the mouth fully, tendency to stick the tongue out of the mouth, slurred speech and abnormal changes in body posture, difficulty concentrating, spinning feeling, shaking, fits, unconsciousness

• Sexual arousal

• Anxiety, agitation, excitability, hostility, aggression, rage, sleep disturbances, seeing or hearing things that are not there-these are more likely to occur in children and the elderly

• Lowered breathing rate, breathe shortness, temporarily stopping breathing, including while asleep, worsening of asthma,

• Constipation

• Changes in liver function-your doctor will check for this

• Changes in your blood-your doctor will check for this

4. Reporting of side effects

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

www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lorazepam

Keep all medicines out of the sight and reach of children.

• Do not use this medicine after the expiry date stated on the pack after Exp. The expiry date refers to the last day of that month.

• Store below 25°C. Protect from moisture and light. Store in the original package.

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 Tablets contain

Lorazepam 1 mg: The active substance is 1mg of Lorazepam. The other ingredients are lactose, colloidal silicon dioxide, starch, sodium starch glycollate, magnesium stearate, and aluminium lake patent blue V (E131).

Lorazepam 2.5 mg: The active substance is 2.5mg of Lorazepam. The other ingredients are lactose, starch, colloidal silicon dioxide, sodium starch glycollate, magnesium stearate, and aluminium lake quinoline yellow (E104).

See end of section 2 for further information on lactose

◆ What Lorazepam Tablet looks like and contents of the pack

Lorazepam 1 mg: Pale blue, oblong shaped tablets with bevelled edge, embossed “L/1” on one face and “PV” on the other face.

Lorazepam 2.5 mg: Yellow oblong tablets with bevelled edge, embossed “L/2.5” on one face and “PV” on the other face.

Pack sizes of Lorazepam 1 mg & 2.5 mg are “14, 28, 30, 50, 56, 100, 250, 500 & 1000” tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Pharmvit Ltd, 177 Bilton Road, Perivale, Greenford, Middlesex UB6 7HQ.

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To request a copy of this leaflet in large print or audio format or additional copies, please contact the licence holder at the address (or telephone, fax) above.

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