Consilient Health

PACKAGE LEAFLET: INFORMATION FOR THE USER

Lorazepam 0.5 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.
- This medicine contains Lorazepam, which can cause dependence, tolerance and addiction. You can get withdrawal symptoms if you stop taking it or reduce the dose suddenly. If this medicine is being used for the treatment of epilepsy you must continue to take this medicine as instructed by your doctor.

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 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.

This medicine has been prescribed for you for anxiety. It contains the Lorazepam which belongs to a class of medicines called benzodiazepines.
This medicine has been prescribed to you and should not be given to anyone else.
Benzodiazepines can cause dependence, tolerance and addiction, and you may get withdrawal symptoms if you stop taking it or reduce the dose suddenly. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months. If this medicine is being used for the treatment of epilepsy you must continue to take it as prescribed by your doctor.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LORAZEPAM

Do not take Lorazepam:
- if you are allergic to lorazepam, other 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 breast-feeding, since the drug may pass into breast milk
- if you are planning a pregnancy or are pregnant.

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

Warnings and precautions
Talk to your doctor or pharmacist before taking Lorazepam if you:
- abuse or have in the past abused drugs or alcohol
- have a personality disorder. If so, you have a greater chance of becoming dependent on Lorazepam
- have any kidney or liver problems
- are suffering from depression, since Lorazepam may increase any suicidal feelings which you may have
- have suffered from depression before, since it could re-occur during treatment with Lorazepam
- suffer from breathing problems
- are suffering from an eye problem called glaucoma e.g. high pressure within the eye.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs, or if you have ever had a history of struggling to control your alcohol or drug intake.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Lorazepam to get the same level of symptom control, this may mean you are developing tolerance to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative medication.

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your prescriber should have explained how long you will be taking it for and, when it is appropriate to stop, how to do this safely. When your treatment is stopped, it is usually done gradually over a period which is specific to you and may occur over a period of weeks to months

Physical dependence and addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include:
- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets 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).

Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.
Benzodiazepines should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of benzodiazepines, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

Lorazepam may also affect the way other drugs work. In particular, you should tell your doctor if you are taking any of the following:
- sedatives (e.g. barbiturates or antihistamines)
- anti-anxiety medicines
- anti-depressants
- strong pain killers (e.g. methadone)
- medicines for epilepsy (e.g. phenobarbital or valproate)
- antihistamines
- medicines for mood or mental disorders (e.g. chlorpromazine, loxapine or clozapine)
- medicines for cataplexy
- medicines for treating HIV
- medicines used to treat delusions or hallucinations
- indigestion medicines (e.g. omeprazole)
- muscle relaxants (e.g. baclofen and tizanidine)
- medicines to treat addiction (e.g. lofexidine and disulfiram)
- medicines to treat tuberculosis (e.g. isoniazid)
- antibiotics (e.g. erythromycin)
- medicines to treat high blood pressure (hypertension)
- medicines to treat Parkinson's disease (e.g. levodopa)
- oestrogen-containing contraceptives
- medicines for asthma (theophylline).

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

Opioids
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 work.

You should not drink alcohol while taking Lorazepam because the sedative effects may be increased, causing you to feel very sleepy.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, 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.

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 or operating machinery by affecting your vision or muscle function.

You should not take part in any 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 0.5 mg tablets contains 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.

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 0.5 mg tablets should be swallowed whole with water.

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The recommended dose is:

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 aged between 5 and 13 years:
- **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.

Children aged less than 5 years:
- Lorazepam is not 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.

Your prescriber should have discussed with you how long the course of tablets will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

If you take more Lorazepam than you should
If anyone has taken more Lorazepam than they should (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 if you need further treatment.
- The number of Lorazepam 0.5 mg tablets and how often you take them should always be reduced slowly before stopping them. This allows your body to 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 headaches, 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 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 suffer from any of these symptoms, ask your doctor for advice immediately. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. This may occur over a period of weeks to months. Your prescriber will ensure that your plan for stopping treatment is tailored to you and can be adapted according to your needs and experience of any withdrawal symptoms.

Withdrawal symptoms such as:
- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets 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).

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, 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):
- 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 problems
- 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 upsets
- Feeling sick (nausea)
- Constipation
- Changes in the amount of saliva in the mouth
- Skin problems such as rashes and inflammation
- Erectile dysfunction
- Blood or liver function changes
- Low blood pressure
- Low body temperature.

Very rare (may affect up to 1 in 10,000 people):
- Trembling or shaking.

Not known (frequency cannot be estimated from the available data):
- Increased risk of falling
- Dependence and addiction (see section "How do I know if I am tolerant or addicted?").

Drug Withdrawal
When you stop taking Lorazepam, you may experience drug withdrawal symptoms, which include:
- headaches, muscle pain, anxiety, tension, depression, restlessness, sweating, confusion or irritability. Do not stop taking your tablets 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).

How do I know if I am tolerant or addicted?
If you notice any of the following signs whilst taking Lorazepam, it could be a sign that you have become addicted.
- You may feel the need to keep taking the medication for longer than your doctor recommended
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.

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 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 after EXP. The expiry date refers to the last day of that month.

Store below 25ºC.

Store in the original package 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 0.5 mg Tablets contain
The active substance is lorazepam.
The other ingredients (excipients) are: Indigo carmine (E-132), polacrilin potassium, lactose monohydrate, microcrystalline cellulose and magnesium stearate.

What Lorazepam 0.5 mg Tablets look like and contents of the pack
Lorazepam 0.5 mg Tablets are light blue, round, biconvex tablets, with "LZ" debossed on one side and plain on the other.
Lorazepam 0.5 mg Tablets are packaged in aluminum/ PVC-ACLAR® (PCTFE) blisters in packages of 28 tablets.

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