Temesta® 2.5mg Tablets/Lorazepam 2.5mg Tablets

(lorazepam)

Your medicine is known by the above names, but will be referred to as Lorazepam Tablets throughout this leaflet. This medicine is also available in 1mg strength.

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine.
- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

In this leaflet:

1) What Lorazepam Tablets are and what they are used for
2) Before you take Lorazepam Tablets
3) How to take Lorazepam Tablets
4) Possible side-effects
5) How to store Lorazepam Tablets
6) Further information

1) What Lorazepam Tablets are and what they are used for

The name of your medicine is Lorazepam Tablets. 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 Tablets are 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 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 doctor 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.

2) Before you take Lorazepam Tablets

Do not take Lorazepam Tablets:
- if you have severe breathing or chest problems
- if you are allergic to benzodiazepines or any of the other ingredients in Lorazepam Tablets (see list under 'What Lorazepam Tablets contain')
- 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 only prescribed Lorazepam Tablets 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 using Lorazepam Tablets:
- if you 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.
- if you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- if you feel you need to take more of Lorazepam Tablets 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 doctor who will discuss your treatment and may change your dose or switch you to an alternative medication.
- 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 suffering from depression, since lorazepam may increase any suicidal feelings which you may have
- if you have suffered from depression before, since it could re-occur during treatment with lorazepam
- 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).

Taking this medicine regularly, particularly for a long time, can lead to physical dependence and addiction. Your doctor 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 doctor 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 doctor 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.

Taking other medicines

Tell your doctor or pharmacist that you are taking lorazepam before taking any other medicine or if you enter hospital for treatment, or if you are taking any other medicines, including those which have not been prescribed by a doctor, since they may affect the way Lorazepam Tablets work.

Lorazepam Tablets 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, anti-depressants, strong pain killers (e.g. methadone), drugs for epilepsy (e.g. phenobarbital or valproate), antihistamines, 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). 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.

Using Lorazepam with food or drink

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

Pregnancy and breast-feeding

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 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.

Important information about some of the ingredients of Lorazepam Tablets.

The 2.5mg Lorazepam Tablet contains the colour tartrazine (E102) which can cause allergic reactions.

Each tablet also contains the equivalent of 0.25mg of potassium. Too much potassium may be harmful if you are on a low potassium diet.

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 Tablets

Always take Lorazepam Tablets exactly as your doctor has told you.

Your doctor 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 doctor 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. The label on your medicine should also tell you. You should 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 Tablets, or suffering unpleasant effects when you stop taking them. (See 'If you stop taking Lorazepam Tablets' section).

The beneficial effect of Lorazepam Tablets 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 Tablets 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 Tablets
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 Tablets
- After you have finished your prescribed treatment with lorazepam, your doctor will decide if 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 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 suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your doctor 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 doctor 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).
- 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, Lorazepam Tablets 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 around 1 in 100 people):
Dizziness, poor muscle control, muscle weakness, fatigue.

Rare (may affect around 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, 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 or low body temperature.

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

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

Drug Withdrawal
When you stop taking Lorazepam Tablets, 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 Tablets, 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 doctor.

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 tablets
- **Keep out of the sight and reach of children.**
- Do not take Lorazepam Tablets after the expiry date which is stated on the carton after EXP.
- The expiry date refers to the last day of the month.
- Do not store above 25°C. Store in the original package.
- Return any unused tablets to your pharmacist. Only keep them if your doctor tells you to.
- If the tablets become discoloured or show any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6) Further information
What Lorazepam Tablets contain
Each tablet contains 2.5mg of Lorazepam.
The other ingredients are lactose monohydrate, cellulose microcrystalline, polacrilin potassium, quinoline yellow aluminium lake E104, magnesium stearate and lactose anhydrous.

What Lorazepam Tablets look like and the contents of the pack
Lorazepam Tablets are yellow capsule-shaped tablets, with 'L Z' on one face and with a break bar on the other face.
Lorazepam Tablets are available in blister packs of 30 tablets.

PL 46420/0348 Temesta 2.5mg Tablets/Lorazepam 2.5mg Tablets **POM**

Who makes and repackages your medicine?
Your medicine is manufactured by Sanofi SRL, S.S. 17 Km 22, 67019 Scoppito, Italy or Laboratoires BTT, Zl de Kraft, 67150 Erstein, France. Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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