Lorazepam Tablets (see list under 'What Lorazepam Tablets contain')

- You have myasthenia gravis, very weak or tired muscles
- You have serious liver problems
- You suffer from sleep apnoea (breathing problems when you are asleep)
- You are breastfeeding, since the drug may pass into breast milk.
- You are planning a pregnancy or are pregnant.
- You have been only prescribed Lorazepam Tablets for anxiety and no other medication, please consult your doctor whether other medications should also be prescribed.

Warning or precautions

- Talk to your doctor before using Lorazepam Tablets:
  - If you have 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 suffer 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

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

Taking other medicines

- Talk to 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), medicines for epilepsy (e.g. phenytoin or valproate), antihistamines, or drugs for mood or mental disorders (e.g. chlorpromazine, loprazolam or clozapine), for the treatment of asthma (theophylline). The dose of these drugs may need to be reduced before you 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. However, this conclusion 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 opioids 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.
- 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), medicines for epilepsy (e.g. phenytoin or valproate), antihistamines, or drugs for mood or mental disorders (e.g. chlorpromazine, loprazolam or clozapine), drugs for the treatment of asthma (theophylline). The dose of these drugs may need to be reduced before you take lorazepam.

Please tell your doctor or pharmacist that you are taking lorazepam before taking any other medication, please consult your doctor whether other medications should also be prescribed.

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, including asthma, especially if you are also allergic to aspirin.

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

- 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 a history of allergy to any of the ingredients of Lorazepam Tablets
- If you have severe liver problems
- If you suffer from sleep apnoea (breathing problems when you are asleep)
- If you are breastfeeding, 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 medication, please consult your doctor whether other medications should also be prescribed.

Warning or precautions

- Talk to your doctor before using Lorazepam Tablets:
  - If you are allergic to benzodiazepines or any of the other ingredients in Lorazepam Tablets
  - If you have any kidney or liver problems
  - If you suffer from depression, since lorazepam may increase any suicidal feelings which you may have

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Taking other medicines

- Talk to 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.

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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.
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Please tell your doctor or pharmacist that you are taking lorazepam before taking any other medication, please consult your doctor whether other medications should also be prescribed.
Children (between 5 and 13 years of age) - Before Surgery: This 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 patients with liver or kidney problems - Older patients may be given lower doses. They may respond to half the usual adult dose 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 11) you stop taking Lorazepam Tablets: Ecce tabletten. 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 will 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 it, but not more than 3 hours since your usual time. If more than 3 hours has passed from when you usually take your tablets, you should 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 take it 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 stop taking your tablets suddenly. This could lead to more serious symptoms such as dizziness, feeling 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, hearing or seeing things, sound or touch, uncontrolled or overactive movements, twitching, shaking, feeling sick, being sick, stomach upsets or stomach pain, loss of appetite, agitation, abnormal fear, heartbeat, panic attacks, dizziness or feeling that you are about to fall, memory loss, hallucinations, feeling stiff and unable to move easily, feeling very relaxed, or convulsions (audible uncontrolled shaking or jerking of the body). - Patients who are depressants and patients with seizure disorders are more likely to experience convulsions. If you suffer from any of these symptoms, ask your doctor for advice immediately. 4. POSSIBLE SIDE-EFFECTS List of 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, rashes, hallucinations, personality changes, sexual anxiety, 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 disorders. Impaired consciousness is e.g. reduced air hunger, confusion, disorientation, fainting as this may lead to coma. Thoughts of harming or killing yourself, becoming dependent on Lorazepam. Several side-effects are e.g. difficulty in breathing, swelling of the lips, tongue, throat, hands, feet and/or severe fairness or dizziness. Jaundice e.g. yellowing of the skin, eyes, rose, male, pale coloured stools (faeces) and dark coloured urine. Other side effects Very common may affect more than 1 in 10 people: Headache Abdominal pain Common may affect around 1 in 100 people. Abnormal and/or increased number, or intensity of dreams. Fatigue Rare may affect around 1 in 1000 people and may need urgent medical attention: Dizziness, tinnitus, hallucinations, memory loss or forgetfulness, problems with vision including double vision or blurred vision, worsening of weak eyes (e.g. lout strong, restlessness and choking/gasping during the night, hearing or seeing things, stomach upsets, nausea and vomiting. 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 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, 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. Lorazepam Tablets should be kept in a cool, dry place. They should be stored safely, where children cannot see or reach them. Return any unused tablets to your pharmacist. Only keep them if your doctor tells you to. These 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 The active substance in both 1mg and 2.5mg tablets is lorazepam. Each tablet contains either 1mg or lorazepam (blue tablets) or 2.5mg lorazepam (yellow tablets). The other ingredients are lactose, microcrystalline cellulose, povidone, magnesium stearate and either indigo carmine (E132) (blue tablet) or tartrazine (E102) (yellow tablet). What Lorazepam Tablets look like and the contents of the pack Lorazepam Tablets are blue (mg) or yellow (2.5mg) capsule-shaped tablets, plain on one face and with a break bar on the other face. Each pack contains 28 tablets. This leaflet was last revised in August 2018.