PACKAGE LEAFLET: INFORMATION FOR THE USER

Lormetazepam Tablets 0.5mg and 1mg

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.

What is in this leaflet:

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

1. WHAT LORMETAZEPAM TABLETS ARE AND WHAT THEY ARE USED FOR

The name of your medicine is Lormetazepam Tablets. Lormetazepam is a member of a group of medicines called benzodiazepines. Lormetazepam is used for short-term therapy to help with sleeping difficulties which are significantly affecting your normal daily life.

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 LORMETAZEPAM TABLETS

Warnings and Precautions:

Talk to your doctor before using Lormetazepam Tablets:
- if you have severe breathing or chest problems
- if you are allergic to benzodiazepines or any of the other ingredients in Lormetazepam Tablets (see list under 'What Lormetazepam 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.

Take special care with Lormetazepam Tablets:
- if you are pregnant, or trying to become pregnant (see below)
- 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 Lormetazepam 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 lormetazepam
- if you have any kidney or liver problems
- if you are suffering from depression, since lormetazepam may increase any suicidal feelings which you may have
- if you have suffered from depression before, since it could re-occur during treatment with lormetazepam
- if you suffer from breathing problems
- if you are suffering from an eye problem called glaucoma.

Lormetazepam 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 lormetazepam 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 Lormetazepam Tablets work.

Lormetazepam Tablets may also affect the way other drugs work. In particular, you should tell your doctor if you are taking any other sedative, anti-anxiety drugs, anti-depressants, anti-hypertensives, strong pain killers (e.g. methadone), drugs for epilepsy, drugs to help breathing, drugs which stop liver enzymes working, anaesthetics, antihistamines or drugs for mood or mental disorders (e.g. chlorpromazine). The dose of these drugs may need to be reduced before you can take lormetazepam.

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.

Pregnancy and breast-feeding

Pregnancy
Do not take this medicine if you are pregnant, or might become pregnant, without consulting your doctor. Benzodiazepines, including lormetazepam, 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.

Breast-feeding
Do not take this medicine if you are breast-feeding, since the drug may pass into breast milk, and may cause the baby to be less active and unable to suckle.

Driving and using machines
Lormetazepam may make you feel dizzy or sleepy during the day, or may affect your concentration. This may affect your performance at skilled tasks such as driving and operating machinery.

You should avoid alcohol while you are taking lormetazepam, since this may make you very drowsy and seriously affect your ability to drive or use machines.

This 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:
  - 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 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 Lormetazepam Tablets
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 LORMETAZEPAM TABLETS

Always take Lormetazepam 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.
The usual adult dose of Lormetazepam Tablets is 0.5mg to 1.5mg. For patients with mild to moderate difficulties in breathing or patients with liver impairment a dose reduction should be considered. You should swallow your tablets with water just before you go to bed at night. Make sure you can have 7 or 8 hours of uninterrupted sleep before taking Lormetazepam Tablets.
Elderly: Elderly patients may respond to half the usual adult dose or less.

The label on your medicine will tell you how many tablets to take and how often. If it does not, or you are not sure, ask your doctor or pharmacist.

Treatment usually lasts from a few days to 2 weeks. It should not usually last longer than 4 weeks including a dose reduction at the end. This reduces the risk of becoming dependent on Lormetazepam Tablets, or suffering unpleasant side-effects when you stop taking them (See 'If you stop taking Lormetazepam Tablets' section).

The beneficial effect of Lormetazepam Tablets may be less apparent after several weeks of use. If you are given lormetazepam for more than 4 weeks, your doctor might want to take blood samples occasionally to check your blood and liver, since drugs like lormetazepam have occasionally affected liver function.

If you take more Lormetazepam Tablets than you should
Do not take more tablets than stated on the label of your medicine. If you take too many tablets you should seek medical attention 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 Lormetazepam Tablets
If you forget to take a dose, don't worry, just take your next tablet when it is due. **Do not take a double dose to make up for a forgotten tablet.**

If you stop taking Lormetazepam Tablets
- After you have finished your prescribed treatment with lormetazepam, your doctor will decide if you need further treatment.
- The number of Lormetazepam 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 lormetazepam, 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, Lormetazepam 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:
Confusion, depression, numbed emotions, difficulty controlling urges and impulses to speak, act or show emotions, a feeling of well-being for no reason, allergic reaction, changes in appetite, sleep problems, changes in sex drive, sexual problems, headaches, reduced alertness, speech problems, memory loss or forgetfulness, problems with vision, worsening of sleep apnoea, difficulty breathing, feeling sick, stomach upsets, changes in the amount of saliva in the mouth, yellowing of the skin and eyes, skin problems such as a rash, dependence to Lormetazepam Tablets, suicidal thoughts or plans, hypersensitivity including anaphylaxis, twitching or shaking, feeling worried or stressed, slow thoughts, coma, feeling very cold, worsening of original sleeplessness and related symptoms such as: restlessness, agitation, irritability, aggressiveness, loss of the sense of reality, intense anger, nightmares, hallucinations and inappropriate behaviour.

Other side effects include:
Very common (may affect more than 1 in 10 people):
Daytime drowsiness, feeling calm and sleepy.
Common (may affect around 1 in 100 people):
Dizziness, muscle weakness, poor muscle control and unsteady movements, general weakness, feeling tired.
Rare (may affect around 1 in 1,000 people):
Blood or liver function changes, low blood pressure.
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 Lormetazepam 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 Lormetazepam 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 LORMETAZEPAM TABLETS

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Do not take Lormetazepam Tablets after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Lormetazepam Tablets should be kept in a cool, dry place. Return any unused tablets to your pharmacist. Only keep them if your doctor tells you to. 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 to protect the environment.

6. FURTHER INFORMATION

What Lormetazepam Tablets contain
The active substance in 0.5mg and 1mg tablets is lormetazepam.
The other ingredients are lactose, maize starch, polyvinylpyrrolidone and magnesium stearate.

What Lormetazepam Tablets look like and contents of the pack
Lormetazepam Tablets are round, white tablets, plain on one side, and with either 'GP036' (0.5mg tablets) or with 'GP037' (1mg tablets) on the other.
Each pack contains 30 tablets.

POM

PL 17225/0012 **Lormetazepam Tablets 0.5mg**
PL 17225/0013 **Lormetazepam Tablets 1mg**

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