2. BEFORE YOU TAKE LORMETAZEPAM TABLETS

Warnings and Precautions:
- Take your doctor or pharmacist that you are taking lormetazepam before taking any other medicine or if you are taking any other medicines, including those which may affect your ability to drive or use machines.
- 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.
- Elderly patients may respond to half the usual adult dose or less.

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 and unable to suckle. 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 may 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.

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 may 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 medicine.

3. HOW TO TAKE LORMETAZEPAM TABLETS

Always take Lormetazepam Tablets exactly as your doctor has told you. 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 1mg. 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 bremzatrione have occasionally affected liver function.

If you take more Lormetazepam Tablets than you should Do not take any tablets more 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 the 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 its 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, tremor, depression, drowsiness, 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 emotions. Some patients have also experienced nightmares or tingling of the arms or legs, tremors (trembling 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, aggression,(abnormally fast heartbeat, panic attacks, dizziness or feeling that you are about to fall; memory loss, hallucinations, feeling still and unable to move easily, feeling very warm, convulsions (uncontrolled shaking or rolling of the body).
- Patients taking antidepressants 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, numbness, drowsiness, difficulty concentrating, urge to impulsively 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 awareness, speech problems, memory loss or forgetfulness, problems with walking, seeing, hearing, swelling of the eyes, skin problems such as: restlessness, agitation, irritability, loss of the sense of reality, intense anger, 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 side effects (may affect more than 1 in 10 people):
  - Daytime drowsiness, feeling calm and sleepy.
  - Loss of appetite.
  - Dizziness, muscle weakness, poor control of unsteady movements, general weakness, feeling faint.
- Rare side effect around 1 in 1,000 people:
  - Drowsiness, ability to function changes, the blood pressure.
- Not known (frequency cannot be estimated from the available data):
  - Nervousness.

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 to the Yellow Card Scheme onmhs.gov.uk/report or search for ‘NHSF Yellow Card’ in the Google Play or App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE LOMETAZEPAM 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, macrogel, poloxamer 188 and magnesium stearate.

What Lormetazepam Tablets look like and contents of the pack

Packaging of Lormetazepam Tablets is round, white tablets, plain on one side, and with either ‘GP036’ (0.5mg tablets) or ‘GP037’ (1mg tablets) on the other.

Each pack contains 30 tablets.

PL 71225/2012
Lormetazepam Tablets 0.5mg
PL 71225/2013
Lormetazepam Tablets 1mg

Marketing Authorisation Holder
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