

Package leaflet: Information for the patient

LOPRAZOLAM 1MG TABLETS

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. 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 gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- Your doctor may have given you this medicine before from another company. It may have looked slightly different. However, either brand will have the same effect.

What is in this leaflet

1. What loprazolam is and what it is used for
2. What you need to know before you take loprazolam
3. How to take loprazolam
4. Possible side effects
5. How to store loprazolam
6. Contents of the pack and other information

1. WHAT LOPRAZOLAM IS AND WHAT IT IS USED FOR

The name of your medicine is Loprazolam 1mg Tablets (called loprazolam throughout this leaflet). Loprazolam contains a medicine called loprazolam mesylate. This belongs to a group of medicines called hypnotics. It works by acting on your brain to help you sleep.

Loprazolam is used to treat sleep problems such as:

- Difficulty falling asleep
- Waking often during the night

Loprazolam is used for short term sleep problems.

Do not use long term. Treatment should be as short as possible because the risk of dependence increases with the duration of treatment.

Ask your doctor for advice if you are unsure.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE LOPRAZOLAM

Do not take this medicine and tell your doctor if:

- You are allergic (hypersensitive) to loprazolam mesylate or any of the other ingredients of this medicine (listed in Section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue
- You are allergic (hypersensitive) to other benzodiazepines such as nitrazepam or temazepam
- You have a problem that causes severe muscle weakness (myasthenia gravis)
- Your lungs do not work properly
- You have heart problems
- You suffer from depression, anxiety or mental problems including phobias and obsessive disorders
- You have ever been addicted to alcohol
- You have a problem where you stop breathing for short periods at night (sleep apnoea)

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking loprazolam.

Warnings and precautions

Talk to your doctor or pharmacist before taking loprazolam if:

- You have any liver problems
- You have any kidney problems
- You have a history of drug abuse
- You have been told by your doctor that you have had or are likely to have a stroke
- You have been told by a doctor that you have a personality disorder
- You have recently taken loprazolam or other similar medicines for more than four weeks
- You do not feel you will ever be able to stop taking loprazolam or other medicines used to treat sleep problems
- You are taking medicines to relieve pain (opioids such as codeine, methadone, morphine, oxycodone, pethidine or tramadol). Your doctor will decide if you should receive loprazolam (see also 'Other medicines' section below).
- You are elderly, as loprazolam can cause drowsiness and decreased consciousness which can lead to falls and severe injuries.

The risk of dependence is greater in patients with a history of mental disorders and/or alcohol or drug abuse. Tell your doctor or pharmacist if you have ever had a mental disorder, or have abused or have been dependent on alcohol or drugs.

Some studies have shown an increased risk of suicidal ideation, suicide attempt and suicide in patients taking certain sedatives and hypnotics, including this medicine.

However, it has not been established whether this is caused by the medicine or if there may be other reasons. If you have suicidal thoughts, contact your doctor as soon as possible for further medical advice.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before taking loprazolam.

Other medicines and loprazolam

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because loprazolam can affect the way some other medicines work. Also some medicines can affect the way loprazolam works.

Tell your doctor if you are taking any of the following:

- Medicines to treat stomach problems such as cisapride
- Medicines which relax muscles (neuromuscular depressants). These are often used during operations or in Intensive Care Units.
- Medicines for mental problems (antipsychotics)
- Medicines for depression
- Medicines for epilepsy (anticonvulsants)
- Medicines used in surgery (anaesthetics)
- Medicines to calm or reduce anxiety or for sleep problems (hypnotics)
- Medicines for hay fever, rashes or other allergies that can make you sleepy (sedative antihistamines) such as chlorphenamine or promethazine
- Some medicines for moderate to severe pain (narcotic analgesics) such as codeine, methadone, morphine, oxycodone, pethidine or tramadol

Taking loprazolam with food and drink

- Do not drink alcohol while you are taking loprazolam.
- Alcohol can increase the effects of loprazolam and make you sleep very deeply so that you do not breathe properly or have difficulty waking.

Pregnancy, breast-feeding and fertility

Use of this medicine is not recommended during pregnancy.

If you discover that you are pregnant or are planning to have a baby, consult your doctor right away to re-assess the need for treatment.

A large amount of data has not shown evidence of malformations associated with the use of benzodiazepines. However, some studies have shown a potentially increased risk of cleft lip and palate in newborn babies compared to that in the general population. Use of this medicine is not recommended during pregnancy.

Cleft lip and palate (sometimes called "harelip") is a deformation at birth caused by incomplete fusion of the palate and upper lip.

Reduced fetal movement and fetal heart rate variability may occur after taking loprazolam during the second and/or third trimester of pregnancy.

If loprazolam is taken at the end of pregnancy, your baby may show muscle weakness (hypotonia or floppy infant syndrome), a drop in body temperature (hypothermia), difficulty feeding (problems suckling causing poor weight gain) and breathing problems (respiratory distress). If taken regularly in late pregnancy, your baby may get withdrawal symptoms such as agitation or shaking. In this case the newborn should be closely monitored during the postnatal period.

Do not take loprazolam if you are breast-feeding or planning to breast-feed. This is because small amounts may pass into mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

This medicine may cause drowsiness, lack of concentration, muscle weakness and memory loss. If this happens do not drive or use any tools or machines.

The 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 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 loprazolam

Lactose: This is a type of sugar. 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 LOPRAZOLAM

Always take loprazolam exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Swallow the tablet whole with a drink of water
- Take just before bedtime
- You should not normally take loprazolam for more than 4 weeks.

Adults

The usual dose is one tablet (1mg) just before bedtime. This dose may be increased by your doctor to one and a half tablets or 2 tablets (2mg).

Elderly or frail people

The starting dose is half a 1mg tablet just before bedtime. This dose may be increased by your doctor to one whole tablet.

Children

Do not give this medicine to children.

If you take more loprazolam than you should

If you take more loprazolam than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack with you. This is so the doctor knows what you have taken.

If you forget to take loprazolam

Loprazolam must only be taken at bedtime. If you forget to take your tablet at bedtime, then you should not take it at any other time, otherwise you may feel drowsy, dizzy and confused during the day.

Do not take a double dose to make up for a forgotten tablet.

If you stop taking loprazolam

Keep taking loprazolam until your doctor tells you to stop. Do not stop taking loprazolam suddenly, but tell your doctor if you want to stop. Your doctor will need to lower your dose and stop your tablets over a period of time.

If you stop taking loprazolam suddenly, your sleep problems may come back and you may get a 'withdrawal effect'. If this happens you may get some of the effects listed below.

See a doctor straight away if you get any of the following effects:

- Feeling anxious, irritable, confused or restless
- Changes in your behaviour
- Depression (low mood)
- Sleep problems
- Headaches

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, loprazolam can cause side effects, although not everybody gets them.

Stop taking loprazolam and see a doctor or go to a hospital straight away if:

- You get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an **allergic reaction** to loprazolam tablets.

Tell your doctor straightaway if you have any of the following side effects:

- Poor memory since taking loprazolam (amnesia)
- Thoughts of harming or killing yourself, depression (low mood)
- Limp or weak muscles
- Behavioural changes. This might include angry outbursts or feeling very excited
- Liver problems that may cause the eyes or skin to go yellow (jaundice)
- Drowsiness and decreased level of consciousness leading to falls and severe injuries in elderly patients.

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

- Skin rash
- Difficulty passing water (urine)
- Feeling unsteady or clumsy
- Feeling sick (nausea), stomach problems
- If you have recently suffered a bereavement you may find it more difficult to cope
- Feeling dizzy, sleepy or confused
- Headache
- Problems with your eyesight such as blurred vision
- Changes in your sex drive
- Feeling dizzy, light headed or faint. These effects are due to low blood pressure
- You get infections or bruise more easily than usual. This could be because of a blood problem (such as agranulocytosis, neutropenia or thrombocytopenia)
- Speech problems.

Reporting of side effects

If you get any side effects, talk to your doctor or 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 LOPRAZOLAM

- Keep out of the reach and sight of children
- Do not store above 25°C
- Do not use loprazolam after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- Store in the original package and protect from light.
- 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. CONTENTS OF THE PACK AND OTHER INFORMATION

What loprazolam 1mg Tablets contain

Each tablet contains 1mg of loprazolam mesylate as the active substance. The other ingredients are lactose, povidone, colloidal silicon dioxide, maize starch, microcrystalline cellulose and magnesium stearate.

What loprazolam looks like and contents of the pack

Loprazolam tablets are light yellow, biconvex, marked with an 'A' and '026', separated by a score line on one side. The other side is blank. They are supplied in cartons of 28 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Zentiva Pharma UK Limited
12 New Fetter Lane
London
EC4A 1JP
United Kingdom

Manufacturer

Opella Healthcare Poland Sp. z o.o.
Oddział w Rzeszowie
ul. Lubelska 52
35-233 Rzeszów
Poland

This leaflet was last revised in: March 2022

© 2022 Zentiva