

NEW ZEALAND CONSUMER MEDICINE INFORMATION

LOXAMINE

Paroxetine Tablets 20mg



What is in this leaflet

This leaflet answers some common questions about LOXAMINE. It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist. All medicines have risks and benefits. Your doctor has weighed the risks of taking LOXAMINE against the benefits they expect it will have for you. If you have any concerns about taking this medicine, ask your doctor or pharmacist. Keep this leaflet with the medicine. You may want to read it again.

What LOXAMINE is used for

Your LOXAMINE tablets contain the active ingredient, paroxetine hydrochloride. Paroxetine belongs to a group of medicines known as selective serotonin reuptake inhibitors (SSRIs).

LOXAMINE is normally used to treat depression and help prevent potential recurrence of the symptoms of depression. Depression is thought to be caused by a chemical imbalance in parts of the brain. This affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing. LOXAMINE works by correcting this chemical imbalance and may help relieve the symptoms of depression.

LOXAMINE is also used to treat the following conditions: Obsessive Compulsive Disorder, Panic Disorder, Social Anxiety

Disorder/Social Phobia, Generalised Anxiety Disorder and Post-traumatic Stress Disorder.

Your doctor, however, may have prescribed LOXAMINE for another purpose. Ask your doctor if you have any questions about why LOXAMINE has been prescribed for you.

LOXAMINE is available only with a doctor's prescription.

Before you take LOXAMINE

When you must not take it

Do not take LOXAMINE if you:

- **are allergic to paroxetine hydrochloride or any other ingredients listed at the end of this leaflet**
- **are taking another medicine for depression called a monoamine oxidase inhibitor (MAOI) or have been taking a MAOI within the last 14 days.** Ask your doctor or pharmacist if you are unsure as to whether or not you are taking a MAOI.
- **are taking thioridazine** (an antipsychotic medicine)
- **are taking pimozide** (an antipsychotic medicine)
- **are taking linezolid** (a medicine used to treat infections).

Before you start to take it

You must tell your doctor if you:

- **are under 18 years of age.** LOXAMINE is not recommended for use in children or adolescents under 18 years of age.

- **have had an allergic reaction to any medicine that you have taken previously to treat your current condition**
- **are pregnant, plan to become pregnant or you are breastfeeding.** Your doctor will discuss with you the risks and benefits of taking LOXAMINE if you are pregnant or breastfeeding.
- **have thoughts about harming yourself (suicidal thoughts or tendencies), or you have had them in the past**
- **have or ever had any other health problems, including:**
 - heart, liver or kidney problems
 - seizures, fits or convulsions (epilepsy)
 - mania (mood with excitement, over-activity and uninhibited behaviour) or a history of mania
 - raised pressure in the eye (glaucoma)
 - problems with bleeding or blood clotting
- **are allergic to any other medicines, foods, preservatives or dyes.**

If you have not told your doctor about any of the above, or any other medical conditions, tell him/her before you start taking LOXAMINE.

Taking other medicines

Tell your doctor if you are taking any other medicines, or have taken any other medicines in the past two weeks, including any that you buy without a prescription from your pharmacy, supermarket or health shop.

Some medicines that may interfere with LOXAMINE include:

- **antidepressant drugs known as:**

- **monoamine oxidase Inhibitors (MAOI'S)** (e.g. phenelzine and tranylcypromine)
- **selective serotonin reuptake inhibitors (SSRI's)** (e.g. citalopram and fluoxetine)
- **tricyclic antidepressants** (e.g. amitriptyline and imipramine)
- **other serotonergic drugs** (e.g. tramadol, fentanyl and lithium)
- **methylonium chloride** (methylene blue)
- **metoprolol** (a medicine used to lower blood pressure)
- **medicines used to regulate your heart beat** (e.g. flecainide and propafenone)
- **medicines used to control epilepsy** (e.g. phenytoin and carbamazepine)
- **antipsychotic drugs** (e.g. thioridazine, perphenazine and pimozide)
- **atomoxetine** (a medicine used to treat attention deficit hyperactivity disorder (ADHD))
- **risperidone** (a medicine used to treat schizophrenia)
- **procyclidine** (a medicine used to treat Parkinson's disease)
- **triptans such as sumatriptan** (a medicine used to treat migraines)
- **warfarin** (a medicine used to prevent blood clots)
- **medicines used to treat inflammation and pain known as non-steroidal anti-inflammatory drugs or NSAIDs** (e.g. ibuprofen, ketotifen)
- **aspirin** (a medicine used to treat inflammation and pain, and to prevent blood clots)
- **linezolid** (a medicine used to treat infections)
- **tamoxifen** (a medicine used to treat breast cancer).

These medicines may be affected by LOXAMINE or may affect how well it works. You may need to take different amounts of your medicine or you may need to take different

medicines. Your doctor will advise you.

Hypericum perforatum (St John's Wort) should be avoided as adverse interactions have been reported with a range of drugs, including antidepressants.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking LOXAMINE.

Ask your doctor or pharmacist if you are not sure about this list of medicines.

How to take LOXAMINE

Follow all directions given to you by your doctor and pharmacist carefully.

How much to take

Take LOXAMINE exactly as your doctor has prescribed.

Your doctor will tell you how many LOXAMINE tablets to take and when to take them each day. It is important that you take LOXAMINE as directed by your doctor. Do not take more than the recommended dose.

It usually takes 2 to 3 weeks before any response to LOXAMINE is noticeable.

For the treatment of depression, the usual daily dose of LOXAMINE is a single oral dose of 20mg daily. Depending on your response and severity of depression, your doctor may increase your dose to a maximum of 50mg daily.

LOXAMINE is not recommended for use in children and adolescents under 18 years of age.

How and when to take it

LOXAMINE tablets should be swallowed whole with a glass of water. **Do not crush or chew the tablets but they can be halved.**

It is recommended that LOXAMINE is taken once daily in the morning, preferably with food.

How long to take it

Your length of treatment will depend on the medical condition for which you require LOXAMINE and your response to it. For depression, treatment is usually continued for at least six months to prevent potential recurrence.

Continue taking LOXAMINE until your doctor tells you to stop.

If you forget to take it

If you forget to take a dose, take it as soon as you remember. **Do not take more than one dose at a time to make up for the dose you missed.** This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, or have any questions, ask your doctor or pharmacist.

Taking your medicine at the same time each day may help you to remember to take it regularly. If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

While you are taking LOXAMINE

Things you must do

Tell all doctors, dentists and pharmacists who are treating you that you are taking LOXAMINE.

If you are about to be started on any new medicine, remind your doctor or pharmacist that you are currently taking LOXAMINE.

If you are pregnant, plan to become pregnant or are breastfeeding, tell your doctor or pharmacist.

When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like LOXAMINE may increase the risk of a serious condition in babies called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after

the baby is born. If this happens to your baby you should contact your midwife and/or doctor immediately.

If you plan to have surgery, including dental surgery, tell your doctor (including surgeon and/or anaesthetist) or dentist that you are taking LOXAMINE.

Keep all appointments you and your doctor have scheduled so that your progress can be followed.

Tell your doctor if you notice any of the following, especially if they are severe, abrupt in onset, or were not part of your presenting symptoms: anxiety, agitation, panic attacks, insomnia (difficulty sleeping), irritability, hostility (aggressiveness), impulsivity, akathisia (restlessness or difficulty sitting still), hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.

Tell your doctor immediately if you have any distressing thoughts (thought of suicide or self-harm) or experiences during this initial period or at any other time.

Do not stop taking LOXAMINE or lower the dose without first checking with your doctor. Stopping LOXAMINE suddenly may cause dizziness, headache and nausea. Your doctor may want you to gradually reduce the amount of LOXAMINE you are taking before stopping completely.

Things you must not do

Do not drive or operate machinery until you know how LOXAMINE affects you. LOXAMINE can cause drowsiness, dizziness or fatigue in some people. Be careful when driving, operating machinery or performing jobs that need you to be alert, until you are certain that LOXAMINE does not affect your performance.

Do not use LOXAMINE to treat any other conditions unless your doctor tells you to.

Do not give LOXAMINE to anyone else, even if they have the same condition as you.

Things to be careful of

Be careful when drinking alcohol while taking LOXAMINE.

Combining LOXAMINE and alcohol may make you more sleepy, dizzy or lightheaded. Your doctor may suggest you avoid alcohol while being treated with LOXAMINE.

There is an increased risk of breaking a bone in people taking medicines like LOXAMINE. This risk is greatest during the early stages of treatment.

LOXAMINE can affect sperm quality. Discuss this with your doctor if necessary.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOXAMINE.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of these side effects.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- nausea, diarrhoea or constipation
- dizziness or drowsiness
- dry mouth
- sweating
- decreased appetite
- difficulty sleeping
- agitation
- tremor
- blurred vision
- yawning
- sexual problems
- weakness or loss of strength
- headache
- fever
- general ill feeling
- itching of the skin
- joint aches
- skin rash
- appearance of blisters on the skin.

These are the more common side effects of LOXAMINE. Mostly they are mild. Your doctor or pharmacist can help you with these side effects.

Tell your doctor as soon as possible if you notice any of the following:

- abnormal bleeding or bruising
- yellowing of the skin and/or eye (also called jaundice).

The above list includes some serious side effects and may require medical attention.

Tell your doctor immediately or go to your nearest Accident and Emergency Centre if you notice any of the following:

- symptoms of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- symptoms of Serotonin Syndrome such as fever, sweating, confusion, agitation, diarrhoea and muscle spasms. Serotonin Syndrome symptoms vary, are not specific and may result from the interaction of LOXAMINE with other medicines, such as SSRIs (refer to *Taking other medicines* section)
- symptoms of "shock" such as rapid, shallow breathing; cold, clammy skin; a rapid, weak pulse; dizziness, weakness and fainting
- heart palpitations, feeling faint or collapsing
- fits or seizures (convulsions)
- seeing, hearing or feeling things that are not there (hallucinations).

These may be serious side effects. You may need urgent medical attention.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you should suffer from any of these side effects or any other undesired effect, please tell your doctor or pharmacist.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

In case of overdose

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Accident and Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken any LOXAMINE by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of LOXAMINE with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Storage

Always keep your LOXAMINE tablets in the original blister pack and out of sight and reach of children. Store in a cool dry place where the temperature stays below 25°C and protect from light, heat and moisture.

Do not store LOXAMINE, or any other medicine, in the bathroom, on windowsills or in the glove box of the car. Do not refrigerate or freeze your LOXAMINE tablets.

Do not use this medicine after the expiry date shown on either the outer pack or blister pack.

Disposal

If your doctor tells you to stop taking LOXAMINE, or your tablets have passed their expiry date, ask your pharmacist what to do with the remaining tablets.

Product Description

What LOXAMINE tablets look like

LOXAMINE tablets are white, round, engraved "P" scoreline "2" on one side and "G" on the other.

Ingredients

Each tablet contains 22.22mg of the active ingredient, paroxetine hydrochloride, corresponding to 20mg paroxetine base.

Each tablet also contains calcium hydrogen phosphate anhydrous, sodium starch glycollate, colloidal anhydrous silica, magnesium stearate, purified talc, titanium dioxide and deanil methacrylate.

If you want to know more

Should you have any questions regarding this product, please contact your doctor or pharmacist.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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