

LOXAMINE

Paroxetine Tablets 20mg

What is in this leaflet

Please read this leaflet carefully before you start taking LOXAMINE.

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). They are thought to work by their action on brain chemicals called amines, which are involved in controlling mood.

LOXAMINE is normally used to treat major depressive disorder (MDD) and help prevent potential recurrence of the symptoms of depression. Major depressive disorder is longer lasting or more severe than the 'low moods' that everyone has from time to time. It is thought to be caused by a chemical imbalance in parts of the brain. This

imbalance 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 corrects the chemical imbalance and so helps relieve the symptoms of major depressive disorder

LOXAMINE may also be used to treat irrational fears, general anxiety and obsessive behaviour. These can also be due to chemical imbalances in parts of the brain.

LOXAMINE may also be used to treat the symptoms of panic attacks. When taken regularly it will help prevent the attacks.

LOXAMINE may also be used to treat patients who may avoid and/or are fearful of social situations (general and social anxiety).

LOXAMINE may also be used to treat patients who suffer from anxiety caused by re-experiencing an extremely traumatic event (Post Traumatic Stress Disorder)

Your doctor may decide that you should continue to use LOXAMINE for some time, even when you have overcome your problem. This should prevent the problem from returning.

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.

The use of this medicine in children and adolescents under the age of 18 years is not recommended.

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,**
- **any other ingredients listed at the end of this leaflet.**

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take LOXAMINE if you have taken it before and become unwell. Tell your doctor or pharmacist before taking the first dose.

Do not take LOXAMINE if you are taking:

- **thioridazine** (an antipsychotic medicine),
- **pimozide** (an antipsychotic medicine),
- **linezolid** (a medicine used to treat infections),
- **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. Examples of MAOIs are phenelzine and tranylcypromine. There may be others so please check with your doctor or pharmacist. Taking LOXAMINE with a MAOI may cause a serious reaction.

- You are taking or have recently taken (within the last two weeks) a medicine called methylthionium chloride (methylene blue).
- You are taking any other medications for the treatment of major depressive disorder or have done so in the last two weeks. Taking LOXAMINE with another antidepressant may cause a serious reaction.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

You must tell your doctor if you:

- have had an allergic reaction to any medicine that you have taken previously to treat your current condition,
- are allergic to any other medicines, foods, preservatives or dyes,
- have thoughts about harming yourself (suicidal thoughts or tendencies), or you have had them in the past.

Occasionally, the symptoms of major depressive disorder or other psychiatric conditions may include thoughts of harming yourself or committing suicide. It is possible that these symptoms may continue or increase until the full antidepressant effect of your medicine becomes apparent. Go to your doctor immediately and tell them if you have any distressing thoughts or experiences during this initial period or at any other time.

- have or ever had any other health problems, including:
 - heart, liver or kidney problems,

- diabetes,
- 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,
- low blood potassium levels,
- low blood magnesium levels.

- You are 18 years or younger. LOXAMINE is not recommended in patients 18 or younger.
- You are over 65 years of age: LOXAMINE may cause a reduction in the amount of sodium within your blood which can lead to sleepiness and muscle weakness. If you experience these symptoms, please consult your doctor as soon as possible.

Tell your doctor if you 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.

LOXAMINE may affect your sperm. Fertility in some men may be reduced while taking LOXAMINE.

Medicines like LOXAMINE may cause symptoms of sexual dysfunction (see Side Effects section). In some cases, these symptoms have continued after stopping treatment.

LOXAMINE should be used with caution in patients at risk of irregular heart beat (e.g. QTc prolongation and Torsades de Pointes). Your doctor may wish to perform tests on the electrical activity of your heart prior to starting or during your treatment.

It is important that you do not stop taking paroxetine suddenly. Paroxetine is a medicine that can have withdrawal side effects if

stopped suddenly (see Effects on stopping LOXAMINE)."

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.

You should also tell any health professional who is prescribing a new medication for you that you are taking LOXAMINE.

Some medicines that may interfere with LOXAMINE include:

- other antidepressant medicines known as:
 - monoamine oxidase Inhibitors (MAOIs) (e.g. phenelzine and tranylcypromine),
 - selective serotonin reuptake inhibitors (SSRIs) (e.g. citalopram and fluoxetine),
 - tricyclic antidepressants (e.g. amitriptyline, nortriptyline, desipramine and imipramine),
- other serotonergic drugs (e.g. tramadol, fentanyl and lithium),
- methylnium 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, phenobarbital, sodium valproate 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 or selegiline (medicines 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, diclofenac, ketoprofen),
- **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),
- **mivacurium, suxamethonium**, medicines used for anaesthesia),
- **pethidine** (a medicine used to relieve pain)
- **dextromethorphan** (a medicine used to suppress cough)
- **cimetidine** (a medicine to treat stomach ulcers),
- **fosamprenavir or ritonavir** (medicines use to treat HIV),
- **rifampicin** (a medicine to treat tuberculosis),
- **Hypericum perforatum (St John's Wort)** should be avoided as adverse interactions have been reported with a range of drugs, including antidepressants,
- **L-tryptophan** (an amino-acid health supplement that can be purchased).

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.

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 carefully all directions given to you by your doctor and pharmacist. They may differ from

the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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 major depressive disorder, social anxiety disorder/social phobia, generalised anxiety disorder and post-traumatic stress disorder, the usual dose of LOXAMINE is 20 mg daily. Depending on your response, your doctor may increase your dose to a maximum of 50mg daily.

For the treatment of obsessive-compulsive disorder, the usual dose of LOXAMINE is 40mg daily, however your doctor may increase your dose up to a maximum of 60mg daily.

For the treatment of panic disorder, the usual dose of LOXAMINE is 40mg daily, however your doctor may increase your dose up to a maximum of 60mg daily.

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.

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it

Continue to take LOXAMINE even if it takes some time before you feel any improvement in your condition.

For depression, the length of treatment will depend on how quickly your symptoms improve. Most antidepressants take time to work, so do not be discouraged if you do not feel better right away. Some of your symptoms may improve in 1 or 2 weeks but it can take up to 4 or 6 weeks to feel any real improvement. Even when you feel well, you will usually have to take LOXAMINE for several months or even longer to make sure the benefits will last.

Continue taking your medicine until your doctor tells you to stop, even if you begin to feel better.

The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return. If your doctor decides to stop LOXAMINE, the dose is gradually reduced before you would stop taking it. Like some other similar medicines, if LOXAMINE is stopped suddenly you may experience some discontinuation side effects.

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.

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 immediately. 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. It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

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, restlessness or difficulty sitting still, hypomania, mania (mood of excitement, over-activity and uninhibited behaviour), worsening of depression.

When LOXAMINE was tested in children under 18 years with major depressive disorder, obsessive compulsive disorder or social anxiety, there were additional unwanted effects to those seen in adults, such as suicidal thoughts, hostile and unfriendly behaviour and

changing moods. The use of LOXAMINE is not recommended to treat major depressive disorder in children under 18, as the drug has not been shown to be effective in this age group. The long-term safety effects of paroxetine in this age group have not yet been demonstrated.

Information from clinical trials has suggested that young adults, particularly those with depression, may be at an increased risk of suicidal behaviour (including suicide attempts) when treated with paroxetine. The majority of attempted suicides in clinical trials in depression involved patients aged 18 to 30 years.

Family and caregivers of children and adolescents being treated with antidepressants for major depressive disorder or for any other condition (psychiatric or non-psychiatric) need to monitor them for the emergence of agitation, irritability, unusual changes in behaviour, as well as the emergence of thoughts of suicide, and to report such symptoms immediately to their doctor. It is particularly important that monitoring be undertaken during the initial few months of antidepressant treatment or at times of dose increase or decrease.

If you or someone you know is demonstrating any of the following warning signs, contact your doctor or a mental health professional right away or go to the nearest hospital for treatment:

- worsening of your depression
- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts at self-harm
- increase in aggressive behaviour, irritability or any other unusual changes in behaviour or mood.

All mentions of suicide or violence must be taken seriously.

Things you must not do

Do not stop taking LOXAMINE or lower the dose without first checking with your doctor. Stopping LOXAMINE suddenly may cause dizziness, anxiety, sleep disturbances, "pins and needles", electric shock sensations or ringing in the ears. Your doctor may want you to gradually reduce the amount of LOXAMINE you are taking before stopping completely.

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.

Do not take monoamine oxidase inhibitor antidepressants (MAOIs) until two weeks after you stop taking LOXAMINE. Examples of MAOIs include phenelzine and tranylcypromine. There may be others so please check with your doctor.

Things to be careful of

Do not drive or operate machinery until you know how LOXAMINE affects you. LOXAMINE can cause drowsiness, dizziness or fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor, or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much LOXAMINE. 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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LOXAMINE. This medicine helps most people, but it may have unwanted side effects in a few people.

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, vomiting or constipation,
- dizziness or drowsiness/sleepiness,
- dry mouth,
- sweating,
- decreased appetite,
- weight gain,
- difficulty sleeping,
- agitation,
- tremor,
- blurred vision,
- yawning,
- sexual problems (In some cases these symptoms have continued after stopping treatment),
- weakness or loss of strength,
- headache,
- fever,
- general ill feeling,
- itching of the skin,

- joint or muscle aches,
- feeling sweaty or shaky,
- abnormal dreams (including nightmares),
- a feeling of restlessness or agitation which may be accompanied by the inability to sit or stand still
- irresistible urge to move the legs (Restless Legs Syndrome),

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

- abnormal bleeding (including nose bleeds) or bruising
- yellowing of the skin and/or eye (also called jaundice),
- sore throat, cold symptoms with fever or chills,
- high pressure inside the eye (acute glaucoma), blurred vision,
- breast milk production when not breastfeeding,
- changes in blood pressure which could make you feel faint and weak,
- mood of excitement, over-activity and uninhibited behaviour (mania)
- confusion or anxiety,
- rash caused by light or a sensitivity to light
- unexplained weight fluctuations (fluid retention),
- panic attacks or feeling as if your thoughts or actions are not your own (depersonalisation),
- involuntary movements,
- painful persistent erection of the penis.

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, blistering, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath,
- muscle spasms or twitches,

- irregular heartbeat or palpitations,
- collapse or loss of consciousness,
- skin rash, which may blister, and looks like small targets (central dark spots surround by a paler area, with a dark ring around the edge) called erythema multiforme,
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome),
- a widespread rash with blisters and skin peeling on much of the body surface (toxic epidermal necrolysis),
- sudden onset of prolonged muscular spasm or twitches, affecting the eyes, head, neck and body,
- sudden eye pain and blurred vision, possibly with feeling ill and vomiting,
- 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,
- sudden increase in body temperature,
- severe convulsions
- heart palpitations,
- feeling faint,
- collapsing,
- fits or seizures (convulsions),
- seeing, hearing or feeling things that are not there (hallucinations),
- thoughts or talk of death or suicide,
- thoughts or talk of self-harm or harm to others,
- any recent attempts at self-harm.

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

An increased risk of bone fractures has been observed in patients taking this type of medicine.

This medicine has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet. Discuss this with your doctor if necessary.

Some of these side effects (for example, changes cholesterol level or changes in sodium levels in your blood) can only be found when your doctor does tests from time to time to check your progress.

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.

Effects on stopping LOXAMINE

The following adverse events may occur when LOXAMINE is discontinued:

- dizziness,
- sensory disturbances such as 'pins and needles', burning sensations, electric shock-like sensations or ringing in the ears
- sleep disturbances, including intense dreams,
- feeling anxious or agitated,
- nausea (feeling sick),
- shaking or tremors,
- confusion,
- sweating,
- headache,
- diarrhoea,
- visual disturbances,
- heart palpitations.

They are more likely to occur if you stop taking LOXAMINE too quickly. Therefore, always consult your doctor before stopping your medicine. For the majority of patients, symptoms go away on their own within a few weeks. However, if you feel that the

unwanted symptoms are too severe, see your doctor who will suggest how to manage stopping treatment more slowly.

After taking LOXAMINE

Storage

Keep your tablets in the box until it is time to take them.

If you take the tablets out of the box, they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store LOXAMINE, or any other medicine, in the bathroom, on windowsills or in the glove box of the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not refrigerate or freeze your LOXAMINE tablets.

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

Active ingredient(s):
Each tablet contains 22.22mg of the active ingredient, paroxetine hydrochloride, corresponding to 20mg paroxetine base.

Inactive ingredient(s):
LOXAMINE also contains:

- calcium hydrogen phosphate anhydrous (granular),
- sodium starch glycolate,
- colloidal anhydrous silica,
- magnesium stearate,
- purified talc,
- titanium dioxide,
- dimethyl aminoethyl methylacrylate copolymer (Eudragit 100).

If you want to know more

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

Who supplies this medicine

LOXAMINE is supplied in New Zealand by:

Viatrix Ltd
PO Box 11-183
Ellerslie
AUCKLAND
www.viatrix.co.nz
Telephone 0800 168 169

Date of Preparation

11 August 2022 (Based on datasheet dated 11 August 2022).