Not known (frequency cannot be estimated from the available data):
- dizziness, headache, tiredness, numbness or tingling or pins and needles (particularly in the hands and feet), shaking
- feeling faint and dizzy when standing up, change in blood pressure
- interference with heart function such as fast heart rate or irregular heart rhythm
- feeling confused, feeling agitated, feeling disorientated (not knowing where you are)
- difficulty sleeping, nightmares, feeling slightly hyperactive
- low blood pressure, signs may include dizziness, fainting, nausea, feeling cold or clammy, confusion and anxiety
- change in sexual function and sex drive, pain in the testicles, breast swelling in men and women, production of breast milk
- low blood sodium, increased or decreased blood sugar levels
- feeling or being sick, dry mouth, constipation, diarrhoea
- skin rashes, skin rash due to sunlight, swollen face
- difficulty passing or retaining water
- blurred or double vision, changes in eyesight.

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

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 Website: 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 Lofepramine Tablets

Blister packs: Store below 25ºC. Store in the original package.
Plastic containers: Store below 25ºC. Keep the bottle tightly closed.

Keep this medicine out of the sight and reach of children.

Do not take this medicine after the expiry date which is stated on the carton or container after EXP. The expiry date refers to the last day of that month.

Do not take this medicine if you notice any visible signs of deterioration.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Lofepramine Tablets contain
- The active substance is lofepramine (as lofepramine hydrochloride). Each tablet contains 70mg lofepramine base (as 76.1mg lofepramine hydrochloride).
- The other ingredients are lactose, maize starch, citric acid, hydrogenated vegetable oil, povidone and glycerol. The coating on the tablets contains opadry purple 03B25514, hypromellose 6cP (E464), carmoisine (E122), indigo carmine aluminium lake (E132), titanium dioxide (E171), sunset yellow FCF aluminium lake (E110), iron oxide red (E172) and macrogol 400.

What Lofepramine Tablets look like and contents of the pack
Lofepramine Tablets are violet-brown film-coated tablets, approximately 10mm diameter.

Lofepramine Tablets come in blister packs of 28, 30, 56 and 100 tablets and in a plastic container of 250 tablets. Not all pack sizes may be marketed.

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Package Leaflet: Information for the patient

Lofepramine 70mg 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1 What Lofepramine Tablets are and what they are used for
2 What you need to know before you take Lofepramine Tablets
3 How to take Lofepramine Tablets
4 Possible side effects
5 How to store Lofepramine Tablets
6 Contents of the pack and other information

1 What Lofepramine Tablets are and what they are used for

Lofepramine belongs to a group of medicines known as antidepressants.

Lofepramine Tablets are used to treat the symptoms of depression. Common symptoms include feelings of worthlessness or deep sadness, difficulty with everyday tasks, sleeping too much or not being able to sleep and feeling anxious.

2 What you need to know before you take Lofepramine Tablets

Do not take Lofepramine Tablets if you:
- are **allergic** to lofepramine, other tricyclic antidepressants such as clomipramine and imipramine, or any of the other ingredients of this medicine (listed in section 6)
- have **severe liver and/or kidney** problems
- are being treated for **heart problems** such as an abnormal heart rhythm or heart block
- are recovering from a recent **heart attack**
- have a mental illness known as **"mania"**
- have untreated **narrow angle glaucoma** (increased pressure in the eye)
- have an **enlarged prostate gland** with trouble passing urine
- are at risk of a **blocked bowel**
- are taking or have taken any **MAOIs** within the last 14 days
- are suffering from **alcohol or drug poisoning**
- are suffering from **mental confusion** (deliria).

Warnings and precautions
Talk to your doctor, pharmacist or nurse before taking Lofepramine Tablets if you:
- are **elderly**
- have **heart, liver** or **kidney problems**
- have been told that you have a rare tumour known as **"neuroblastoma"** or **"phaeochromocytoma"**
- have a condition called **"porphyria"**
- have ever had **epilepsy, fits or convulsions**
- have any other **mental illness**
- have an **overactive thyroid gland**
- have been told that you have a **blood disorder**
- have **high blood pressure** (hypertension)
- have increased pressure in the eye **(narrow angle glaucoma)**
- have a history of **prostate gland** problems
- are receiving **electroconvulsive therapy** for your depression.

The use of Buprenorphine together with Lofepramine can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Lofepramine Tablets').

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

Prolonged QT interval
A heart problem called "prolonged QT interval" (which is shown on your electrocardiogram, ECG) and heart rhythm disorders (rapid or irregular heartbeat) have been reported with Lofepramine Tablets. Tell your doctor if you:
- have slow heart rate, or there is family history of QT prolongation
- have or had a problem where your heart cannot pump the blood around your body as well as it should (a condition called heart failure)
- are taking any other medication that may cause heart problems
- have a problem that gives you a low level of potassium or magnesium, or a high level of potassium in your blood
- have a surgery planned as it might be necessary to stop the treatment with lofepramine before you are given anaesthetics. In the case of acute surgery, the anaesthetist should be informed about the treatment of lofepramine
- have an overactive thyroid gland or receive thyroid medication.

Thoughts of suicide and worsening of your depression or anxiety disorder
If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this if:
- you have previously had thoughts about killing or harming yourself
- you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away**.

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents
Lofepramine is not suitable for use in children or adolescents under the age of 18.

Other medicines and Lofepramine Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription:
- medicines called monoamine oxidase inhibitors (used to treat depression). You should **not** take lofepramine if you are taking these medicines or you have done so in the last 14 days
- other antidepressants called serotonin reuptake inhibitors 'SSRIs' (e.g. fluvoxamine, fluoxetine)
- medicines that may interfere with the electrical conduction of the heart such as certain antibiotics (e.g. macrolides), anti-malarials, anti-histamines or medicines used to treat psychiatric problems or depression (e.g. phenothiazines and clozapine)
- cold remedies, nasal decongestants or other medicines containing adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephedrine
- medicines which make you feel sleepy or less alert (e.g. sleeping pills, tranquilisers and hypnotics) and alcohol
- medicines to treat thyroid problems
- medicines used to treat high blood pressure (e.g. guanethidine, clonidine, methyldopa, diuretics, diltiazem, verapamil)
- medicines to treat abnormal heartbeats (e.g. amiodarone, disopyramide, procainamide, propafenone, quinidine, sotalol)
- medicines to treat epilepsy
- strong painkillers (e.g. nefopam, tramadol, codeine or morphine)
- buprenorphine (a drug used for severe pain or opioid drug addiction). This medicine may interact with lofepramine and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms
- rifampicin (used for serious bacterial infections such as tuberculosis)
- anti-cholinergics – used to treat Parkinson's disease, irritable bowel syndrome, bladder problems, asthma
- medicines to thin the blood
- medicines to treat certain mental illnesses (e.g. pimozide, sertindole)
- medicines for treating HIV infections (e.g. ritonavir)
- medicines for anxiety (e.g. alprazolam)
- medicines for treating Parkinson's disease (e.g. levodopa, entacapone, selegiline)
- muscle relaxants such as baclofen
- cimetidine (to treat indigestion or a stomach ulcer)
- certain medicines for angina (e.g. diltiazem, verapamil and "nitrates")
- oestrogens or progestogens (e.g. hormone replacement therapy and oral contraceptives).

If you are going to have an operation or dental procedure, tell your doctor or other medical staff that you are taking Lofepramine Tablets. Anaesthetics, such as atropine, may react with Lofepramine Tablets.

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Lofepramine Tablets with food and drink
Swallow the tablets with a drink of water.
You should not drink alcohol whilst taking this medicine as it may affect you more than usual.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Lofepramine Tablets are not recommended if you are pregnant or breast-feeding.
Babies born to mothers who have taken tricyclic antidepressants may suffer from withdrawal symptoms, difficulty in breathing and agitation.

Driving and using machines
Lofepramine Tablets may cause dizziness or drowsiness especially when you first start taking this medicine. If you suffer from any of these side effects, do not drive or operate machinery.

Lofepramine Tablets contain Lactose, Sunset yellow and Carmoisine
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains colouring agents sunset yellow FCF (E110) and carmoisine (E122). These may cause allergic reactions.

3 How to take Lofepramine Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Adults: The recommended dose for adults is one tablet to be taken 2 or 3 times a day.

Elderly: Elderly patients may be prescribed lower doses.

Use in children and adolescents: Lofepramine Tablets are not recommended for children.

Swallow the tablets with a drink of water.

Keep taking your medicine until your doctor tells you to stop.

If you take more Lofepramine Tablets than you should
If you (or someone else) swallow a lot of the tablets together, or if you think your child has swallowed any of the tablets, tell your doctor or go to the nearest hospital casualty department immediately.

If you forget to take Lofepramine Tablets
If you forget to take a dose, take it as soon as you remember. Do not take a double dose to make up for a forgotten dose. If you are unsure, speak to your doctor.

If you stop taking Lofepramine Tablets
Do not suddenly stop taking the tablets as this may cause problems such as sleeplessness, agitation and sweating. When you are feeling better, talk to your doctor before stopping Lofepramine Tablets.

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

4 Possible side effects

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

Stop taking Lofepramine Tablets and see a doctor or go to your nearest hospital casualty department immediately if you experience any of the following serious side effects:
Not known (frequency cannot be estimated from the available data):
- an allergic reaction. Signs may include swelling of your face, lips, tongue or throat or difficulty breathing or swallowing, severe itching of your skin with raised lumps
- you feel more depressed, including thinking about suicide
- delusions and hearing or seeing things that are not there (hallucinations)
- hepatitis including changes in liver function that would be identified by a blood test, yellowing of the skin and the whites of your eyes (jaundice)
- glaucoma (raised pressure in the fluid inside the eye).

Rare (may affect up to 1 in 1,000 people):
- convulsions (fits)
- a serious effect on your blood. Signs of blood disorders may include fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises. If you notice any of these, tell your doctor straight away.

Other side effects
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.

Rare (may affect up to 1 in 1,000 people):
- inappropriate secretion of the hormone ADH (antidiuretic hormone) that may make you pass water (urinate) more frequently
- drowsiness, impairment of sense of taste
- bleeding from the skin, sweating
- swelling of the moist areas of the body such as the nose.

Very rare (may affect up to 1 in 10,000 people):
- difficulty in co-ordinating movements
- buzzing or ringing in the ears.

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