

- low salt (sodium) in the blood which may cause weakness, confusion or difficulty thinking. Other symptoms might include loss of appetite, nausea, vomiting or headaches
- enlargement of one or both breasts in men
- production of breast milk in women who are not pregnant or breast-feeding
- pain in testicles
- effects on sexual function
- mental change called hypomania (feeling elated or emotionally "high")
- uncoordinated movement
- changes in sense of taste
- ringing in the ears
- increased sensitivity to the sunlight.

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

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 at: www.mhra.gov.uk/yellowcard

By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Lofepamine tablets

Blister packs: Store below 25°C. Store in the original package.

Plastic containers: Store below 25°C. Keep the bottle tightly closed.

Keep out of the sight and reach of children.

Do not use Lofepamine Tablets 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 use Lofepamine Tablets if you notice any visible signs of deterioration.

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 Lofepamine 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 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 Lofepamine Tablets look like and contents of the pack

Lofepamine Tablets are violet brown film-coated tablets.

Lofepamine 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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This leaflet was last revised in
October 2018

If you would like a leaflet with larger text, please contact 01271 385257.

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Package Leaflet: Information for the user

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

1 What Lofepamine tablets are and what they are used for

Lofepamine belongs to a group of medicines known as antidepressants.

Lofepamine 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 Lofepamine tablets

Do not take Lofepamine Tablets if you:

- are **allergic** (hypersensitive) to lofepramine, other tricyclic antidepressants such as clomipramine and imipramine, **or any** of the other ingredients of Lofepamine Tablets. An allergic reaction can include a rash, itching or shortness of breath
- 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"**.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Lofepamine 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 increased pressure in the eye (**narrow angle glaucoma**)
- have a history of **prostate gland** problems
- are receiving **electroconvulsive therapy** for your depression.

If you have any thoughts of suicide or harming yourself whilst taking this medicine, you should contact your doctor immediately (see Section 4 – Possible Side Effects).

Other medicines and Lofepamine tablets

Tell your doctor or pharmacist if you are taking, have taken or might take any other medicines:

- 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)
- cold remedies, nasal decongestants or other medicines containing adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephedrine or phenylpropanolamine
- 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, debrisoquine, clonidine, diuretics, diltiazem, verapamil, sotalol)
- medicines to treat abnormal heart beats (e.g. amiodarone, disopyramide, procainamide, propafenone, quinidine, sotalol, digitalis glycosides)
- medicines to treat epilepsy
- strong painkillers (e.g. nefopam, tramadol, codeine or morphine)
- 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 (e.g. warfarin)
- antimalarials (e.g. halofantrine)
- medicines to treat certain mental illnesses (e.g. pimozone, sertindole, clozapine)
- medicines for treating HIV infections (e.g. ritonavir)
- medicines for anxiety (e.g. alprazolam)
- antihistamines (for treating allergies)
- medicines for treating Parkinson's disease (e.g. levodopa, biperiden, entacapone)
- muscle relaxants such as baclofen
- cisapride (for stomach disorders)
- altretamine (for advanced ovarian cancer)
- cimetidine (to treat indigestion or a stomach ulcer)
- certain medicines for angina (e.g. diltiazem, verapamil and "nitrates")
- disulfiram (for treatment of alcohol dependence)

- estrogen (e.g. hormone replacement therapy and oral contraceptives).

Tell your doctor that you are taking Lofepamine tablets if you are going to have an operation. Anaesthetics may react with Lofepamine Tablets.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Lofepamine Tablets with food and drink

Swallow the tablets with a drink of water. You should not drink alcohol whilst taking this medicine.

Pregnancy and breast-feeding

Lofepamine Tablets are not recommended if you are pregnant or breast-feeding.

Driving and using machines

Lofepamine 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.

Lofepamine Tablets contains Lactose and Sunset yellow and Carmoisine

This medicine also contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

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

3 How to take Lofepamine tablets

Always take this medicine exactly as your doctor or pharmacist has told you. You should 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:

Lofepamine 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 Lofepamine 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 Lofepamine 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 Lofepamine 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 Lofepamine Tablets.

4 Possible side effects

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

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 thoughts 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.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) 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.

If you have any of the following side effects you should tell your doctor immediately:

- An allergic reaction: signs are swelling of the lips, face and tongue, difficulty in breathing, feeling faint, rash or itching (affecting the whole body)
- Unusual bruising or bleeding of the skin, mouth, nose or vagina
- Feeling feverish, unusually tired or generally unwell, or you have a sore throat or sore tongue (you may have a blood disorder)
- Your skin or eyes start turning yellow or you have severe stomach ache (you may have a liver problem or jaundice)
- You have a "fit" (seizure).

The following side effects have also been reported. Tell your doctor if you get any troublesome symptoms that you think are side effects.

- low blood pressure
- an irregular or fast heartbeat (pulse)
- dizziness
- sleeping difficulties
- drowsiness
- agitation
- confusion
- hallucinations
- headache
- pins and needles
- generally feeling unwell
- dry mouth
- constipation
- problems with the eyesight
- problems passing water
- sweating
- shakiness or tremor
- nausea (feeling sick)
- vomiting (being sick)
- changes of blood sugar level