PACKAGE LEAFLET
Lofepramine 70 mg Film-coated Tablets
lofepramine

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 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Lofepramine is and what it is used for
2. What you need to know before you take Lofepramine
3. How to take Lofepramine
4. Possible side effects
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1. What Lofepramine is and what it is used for

Lofepramine belongs to a group of medicines known as tricyclic antidepressants. This medicine is believed to work by increasing the levels of two naturally occurring chemicals within the brain, noradrenaline and 5 hydroxytryptamine (also called serotonin).

Lofepramine is used to help relieve the symptoms of depression.

2. What you need to know before you take Lofepramine

Do not take Lofepramine if you:

- are allergic to lofepramine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- have taken other tricyclic anti-depressants, such as imipramine and suffered an unusual or allergic reactions
- have severe liver or kidney disease
- suffer from mania (feeling over-excited with unusual behaviour)
- are being treated for a heart disease such as an arrhythmia (abnormal heart rhythm)
- have a blockage of the electrical conduction system of the heart (heart block)
- are recovering from a heart attack
- have narrow-angle glaucoma (high pressure in the eye) that is not being treated
- have an enlarged prostate gland causing problems with passing urine
- have chronic constipation, especially if you are elderly or bed-ridden, as you are at risk of developing a blockage in the intestine (paralytic ileus)
- are taking any of the following medicines:
  * a monoamine oxidase inhibitor (MAOI) used to treat depression or within 2 weeks before or 2 weeks after you take a MAOI
* amiodarone (to treat an irregular heart rhythm)
* terfenadine (an antihistamine)

If you are unsure if any of the above applies to you, please consult your doctor or pharmacist.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Lofepramine if you:

- suffer from a condition caused by a tumour of the adrenal gland (e.g. phaeochromocytoma or neuroblastoma)
- have liver or kidney disease
- have ever had an epileptic seizure (a fit)
- have recently stopped drinking alcohol
- have a blood disorder or porphyria (a rare blood pigment disorder)
- are having electroconvulsive therapy
- know that you have high blood pressure (hypertension)
- have a heart condition known as ‘congenital long QT syndrome’, or a family history of QT prolongation, which is a disturbance of the heart rhythm
- have any other heart disorder
- have an overactive thyroid gland and are taking medicine to treat the condition
- have ever had raised pressure in the eye (in particular an eye condition called narrow-angle glaucoma)
- have ever had an enlarged prostate gland.
- have in the past suffered from mania (feeling over-excited with unusual behaviour)

During treatment, if you are going to be given a general anaesthetic for an operation or a local anaesthetic for a small operation or dental procedure, tell your doctor or dentist you have been taking lofepramine, as this medicine may increase the risk of side effects.

**Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have any 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
- 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.

**Other medicines and Lofepramine**

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

The following medicines **must not** be taken with lofepramine:

- monoamine oxidase inhibitors (MAOIs) used to treat depression, e.g. moclobemide, selegiline, phenelzine
- terfenadine, an antihistamine used to treat allergic conditions
amiodarone, used to treat problems with heart rhythm

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

- other antidepressants e.g. fluvoxamine, fluoxetine, sertraline, paroxetine
- medicines to treat mental health conditions e.g. chlorpromazine, levomepromazine
- alprazolam, to treat anxiety
- sedatives including barbiturates
- medicine to control heart rhythms e.g. disopyramide, procainamide, propafenone, quinidine or sotalol
- medicines that cause problems with the electrical signals in the heart, such as some antibiotics known as macrolides (e.g. clarithromycin, azithromycin, erythromycin) or medicines to treat or prevent malaria
- medicine to lower high blood pressure e.g. guanethidine, betanidine, reserpine, clonidine, methyldopa
- medicines that can lower potassium levels in the blood, such as diuretics. These include ‘loop’ diuretics such as furosemide, commonly used to treat high blood pressure, and thiazide diuretics such as hydrochlorothiazide, which are mainly used to treat heart failure
- other medicine for high blood pressure or heart conditions e.g. digoxin, verapamil, diltiazem
- ‘sublingual’ tablets to treat angina, e.g. glyceryl trinitrate, as lofepramine can cause a dry mouth so the tablets may not dissolve under the tongue properly
- medicine containing atropine, adrenalin, ephedrine, isoprenaline, noradrenaline, phenylephedrine, phenylpropanolamine
- altretamine to treat ovarian cancer
- medicines to control epilepsy, e.g. lamotrigine, gabapentin, pregabalin
- disulfiram, used to treat alcoholism
- medicines to treat Parkinson’s disease e.g. biperiden, procyclidine
- medicine to thin the blood (anticoagulants) such as warfarin
- cimetidine to treat ulcers or heartburn
- rifampicin, a medicine to treat serious infections such as tuberculosis
- ritonavir, for the treatment of HIV infection
- cold remedies particularly decongestants or hayfever preparations painkillers
- medicines for treatment of thyroid problems
- oral contraceptives or hormone replacement therapy containing oestrogens or progestogens
- antihistamine medicines for treatment of allergic conditions

Lofepramine with alcohol
Do not drink alcohol whilst taking this medicine. Alcohol can make the feeling of drowsiness worse.

Pregnancy, breast-feeding
Do not take lofepramine if you are pregnant, think you may be pregnant or are trying to become pregnant.

Ask your doctor or pharmacist for advice before taking lofepramine.
Driving and using machines
Do not drive or operate machinery if you feel dizzy or drowsy or you have eyesight problems while taking this medicine.

Lofepramine 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 the colouring agent ponceau 4R (E124), which may cause allergic reactions.

3. How to take Lofepramine

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. You should take your tablets as long as your doctor says. Remember that you may need to take Lofepramine for 2 to 4 weeks before you begin to feel better. So do not stop taking this medicine just because you do think that it is not working.

The tablets should be swallowed with a drink of water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

The recommended dose is:

Adults: the usual starting dose is two tablets daily (one in the morning and one in the evening). After a short time, your doctor may tell you to increase the dose to three tablets a day. If this happens, ask your doctor when to take the third tablet.

Elderly: your doctor may give you a lower dose.

Use in children: Lofepramine is not suitable for children.

If you take more Lofepramine than you should contact your doctor or nearest hospital emergency department immediately. Take the container and any remaining tablets with you.

If you forget to take Lofepramine take the next dose as soon as you remember unless it is almost time for your next dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Lofepramine - speak to your doctor first before stopping this medicine. Your doctor will tell you how to gradually reduce your medicine. This will help avoid unwanted side effects such as sleeplessness, excessive sweating or feeling agitated.

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

4. Possible side effects

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

If you notice any of the following side effects, stop taking this medicine and contact your doctor or go to the nearest hospital casualty department straight away:
Rare (may affect up to 1 in 1,000 people):
- unusual bruising or bleeding of the skin, feel feverish or unusually tired, have a sore throat or sore tongue (which may mean you have a blood disorder)
- unusual secretion of ADH, a hormone that causes the body to retain water and dilute the blood, causing a lower than normal level of sodium in the blood, which may make you feel weak and confused with aching muscles
- fits (convulsions)

Not known (frequency cannot be estimated from the available data):
- feelings or thoughts of harming or killing yourself, worsening of your depression or anxiety, or changes in your behaviour
- increased pressure in the eye (glaucoma)
- serious or changes to the heart’s rhythm, causing ‘missed’ or ‘skipped’ beats, or sudden increase in heart rate (QT prolongation or ‘Torsade de Pointes’)
- worsening of existing heart failure
- yellowing of the skin and whites of the eyes (jaundice), stomach pain with fever, dark urine or pale stools, which may be signs of serious liver problems
- inability to pass urine or to empty the bladder

Other possible side effects:

Rare (may affect up to 1 in 1,000 people):
- feeling over-excited
- drowsiness
- taste changes
- bleeding into the skin
- excessive sweating
- change in sex drive or sexual function
- swelling or tenderness of the breasts (in men)
- leaking of breast milk (in men and in women)
- irritation of the lining of the mouth, nose, wind pipe, intestines, stomach or urinary tract
- changes in blood glucose levels (shown in blood test)

Very rare (may affect up to 1 in 10,000 people):
- reduced coordination of movement
- ringing in the ears

Not known (frequency cannot be estimated from the available data):
- dry mouth, feeling or being sick, diarrhoea, constipation
- blurred vision or difficulty focussing, dilated pupils
- dizziness, headache, tingling or prickling feeling (pins and needles), shaking
- low blood pressure
- changes to heart rhythm, especially an increase in heart beat
- difficulty in urinating
- feeling anxious or agitated, mood swings, confusion, seeing or hearing things that are not there (hallucinations)
- difficulty sleeping, nightmares
- feeling generally unwell
- skin rashes or skin allergies, sensitivity of skin to light
- swelling of the face
- pain in the testicles
- increased levels of liver enzymes, seen in a blood test

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 or pharmacist. 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](http://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 Lofepramine**

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

Do not use this medicine after the expiry date, which is stated on the pack after Exp. The expiry date refers to the last day of that month.

Store in the original package in order to protect from light and moisture.

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 to protect the environment.

6. **Contents of the pack and other information**

**What Lofepramine contains**

- The active substance is lofepramine. Each film-coated tablet contains 70 mg lofepramine as the hydrochloride.
- The other ingredients (excipients) are lactose, maize starch, ascorbic acid, talc, glycerol, glycerol monostearate 40-55, disodium edetate, dimeticone, hypromellose, colloidal anhydrous silica. The film-coating also contains: propylene glycol, hypromellose, ponceau 4R (E124), titanium dioxide (E171), indigotine (E132)

**What Lofepramine Tablets look like and contents of the pack**

Your medicine comes as a round, biconvex, violet-brown film-coated tablet, approximately 10 mm diameter and with a score line on one side.

The tablets are available in blister packs of 28, 56, 1008, 2016 tablets or in tablet containers in packs of 56, 250, 500 and 1000 tablets or in amber glass bottle in packs of 56 tablets.

Not all sizes may be marketed.
Marketing Authorisation Holder
Mylan, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom

Manufacturer
McDermott Laboratories Ltd., T/A Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.
Generics [UK] Limited, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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