

Package leaflet: Information for the user

Lofepramine 70mg/5ml Oral Suspension

- **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 your 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 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
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1. What Lofepramine is and what it is used for

The name of your medicine is Lofepramine 70mg/5ml Oral Suspension (called Lofepramine in this leaflet). This belongs to a group of medicines called tricyclic antidepressants.

Lofepramine alters the levels of chemicals in your brain to relieve the symptoms of depression.

Lofepramine can be used to treat the symptoms of depression.

2. What you need to know before you take Lofepramine

Do not take Lofepramine and tell your doctor if:

- you are allergic (hypersensitive) to lofepramine, other tricyclic antidepressants such as clomipramine and imipramine or any other ingredients in this liquid (listed in section 6). An allergic reaction can include a rash, itching or shortness of breath
- you are pregnant, likely to become pregnant or breast-feeding
- you suffer from periods of increased and exaggerated unusual behaviour (mania)
- you have liver or kidney disease
- you have heart problems including unusual heart beats, heart block or if you have recently had a heart attack
- you have untreated glaucoma (raised pressure of the fluid inside the eye)
- you suffer from prostate problems and have problems passing urine
- you suffer from chronic constipation
- you are suffering from alcohol or drug poisoning
- you are suffering from mental confusion (delirium)

- you are taking MAOIs, amiodarone or terfenadine (see ‘Other medicines and Lofepramine’ section).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor before taking Lofepramine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Lofepramine if:

- you have epilepsy or you are experiencing withdrawal from alcohol or epileptic drugs
- you have an enlarged prostate gland
- you have increased pressure in your eye (known as narrow-angle glaucoma)
- you have thyroid problems or you are taking medicine to treat a thyroid problem
- you have a mental illness such as manic depression
- you are having electroconvulsive therapy (ECT)
- you have a problem with your blood called porphyria or other blood problems
- you have tumour of the adrenal gland (phaeochromocytoma or neuroblastoma)
- you have high blood pressure. Your doctor may want to check your blood pressure before starting you on treatment with lofepramine
- you or members of your family have a history of irregular heart beats or other heart problems
- you have been told by your doctor that you have low sodium or potassium levels.

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

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

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. This is because these medicines all take about two weeks but sometimes longer to work properly.

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.

Having operations and tests

Tell your doctor, anaesthetist or dentist that you are taking lofepramine if you are going to have an anaesthetic for an operation or dental treatment.

Other medicines and Lofepramine

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

Do not take Lofepramine if you are taking the following medicines:

- medicines to treat depression known as Monoamine Oxidase Inhibitors (MAOIs) such as phenelzine or you have taken MAOIs within the last 14 days
- pimozide and sertindole, anti-psychotics used to treat schizophrenia
- amiodarone, used to control the way your heart beats
- terfenadine, used to treat allergies
- entacapone, used to treat Parkinson's disease.

In particular tell your doctor if you are taking any of the following medicines:

- other medicines used to treat depression including Serotonin Selective Reuptake Inhibitors (SSRIs) such as fluoxetine and fluvoxamine or drugs that control your moods or alprazolam which makes you feel less anxious
- medicines used to treat pain and addiction called opioids such as buprenorphine or buprenorphine / naloxone combination. These medicines 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 if you experience such symptoms
- medicines that may interfere with the electrical conduction of the heart such as certain antibiotics (e.g. macrolides), anti-malarials (e.g. halofantrine), anti-histamines or medicines used to treat psychiatric problems or depression (e.g. phenothiazines and clozapine)
- medicines used to treat heart problems such as:
 - guanethidine, betanidine, reserpine, clonidine and methyldopa, or other medicines used to treat high blood pressure
 - calcium channel blockers such as diltiazem or verapamil
 - digoxin
 - nitrates used to treat angina
 - medicines that control the heart beat such as sotalol, disopyramide, procainamide, propafenone and quinidine
- warfarin used to prevent your blood clotting. Your doctor may want to perform some tests
- diuretics (water tablets)
- medicines used to treat anxiety or difficulty in sleeping.

Also:

- medicines found in cough and cold remedies such as phenylephrine or phenylpropanolamine. Tell your pharmacist that you are taking lofepramine before buying these medicines
- medicines used to treat epilepsy including barbiturates such as phenobarbital
- medicines that lower blood potassium levels such as diuretics, e.g. loop diuretics, (e.g. furosemide) which are commonly used to treat high blood pressure or thiazide diuretics (e.g. hydrochlorothiazide) which are mainly used to treat heart failure
- disulfiram - used to treat patients with alcohol problems
- medicines used to treat Parkinson's disease (e.g. selegiline)
- ritonavir - used to treat HIV
- cimetidine and cisapride - used to treat stomach acid problems
- medicines to treat thyroid problems
- altretamine used to treat ovarian cancer
- rifampicin used to treat tuberculosis (TB)
- oral contraceptives
- painkillers (e.g. tramadol and nefopam)
- baclofen – a muscle relaxant.

Lofepramine with food, drink and alcohol

Do not drink alcohol whilst taking Lofepramine.

Pregnancy and Breast-feeding

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

Babies born to mothers who have taken tricyclic antidepressants may suffer from withdrawal symptoms, difficulty in breathing and agitation.

Talk to your doctor before breast-feeding because Lofepramine passes into breast milk.

Driving and using machines

Lofepramine may make you feel drowsy. If you experience this, do not drive or use machinery. The amount of alcohol in Lofepramine may also affect your ability to drive or use machines.

Lofepramine contains methyl parahydroxybenzoate, propyl parahydroxybenzoate, liquid maltitol, sorbitol, propylene glycol and ethanol.

- methyl (E218) and propyl parahydroxybenzoates (E216). May cause allergic reactions (possibly delayed).
- liquid maltitol (E965) and sorbitol (E420)(types of sugar). This medicine contains 1.36g sorbitol in each 5ml spoonful. Sorbitol is a source of fructose. If your doctor has told you that you have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you take or receive this medicine.
- propylene glycol (E1520). This medicine contains 108.4mg propylene glycol in each 5ml dose.

- ethanol (alcohol). This medicine contains 395mg of alcohol in each 5ml spoonful which is equivalent to 10ml of beer or 4ml of wine. The amount of alcohol in this medicine is not likely to have an effect in adults. The alcohol in this medicine may alter the effects of other medicines. Talk to your doctor or pharmacist if you are taking other medicines. If you are pregnant or breast-feeding or if you are addicted to alcohol, talk to your doctor or pharmacist before taking this medicine.
- this medicine contains less than 1mmol sodium (23mg) per 5ml dose, that is to say essentially 'sodium free'.

3. How to take Lofepamine

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

Taking this medicine

- this medicine contains 70mg of lofepramine in each 5ml
- take this medicine by mouth
- shake the bottle well before using.

The usual doses are given below. These may be changed by your doctor:

Adults

The usual dose is 70mg (5ml of suspension) two to three times a day.

Older people

Your doctor will start you on a lower dose and gradually increase it as you may be more sensitive to the medicine.

Children

This medicine should not be used in children.

If you take more Lofepamine than you should

If you take more of this medicine than you should, talk to a doctor or go to your nearest hospital straight away. Take the medicine pack with you.

If you forget to take Lofepamine

- If you forget a dose, take it as soon as you remember it. However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose (two doses at the same time) to make up for a forgotten dose.

If you stop taking Lofepamine

Do not stop taking the medicine unless your doctor tells you to. If you stop taking the medicine abruptly, you may get withdrawal effects such as feeling irritable, unable to sleep and sweating more than usual.

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.

Stop taking Lofepramine and see a doctor straight away if you have:

- 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
- a serious effect on your blood, such as low sodium levels. Signs may include fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruises. These may also be signs of other blood disorders. If you notice any of these, tell your doctor straight away.

Serious side effects: tell a doctor straight away

- If you feel more depressed, including thinking about suicide.

If you get any of the following side effects, see your doctor as soon as possible:

- **Effects on your heart:** feeling faint and dizzy when standing up, change in blood pressure, fast or unusual heart beats, heart failure becoming worse
- **Effects on your brain and nervous system:** feeling confused, feeling agitated, feeling disorientated (not knowing where you are), delusions and hearing or seeing things that are not there (hallucinations), difficulty sleeping, nightmares, feeling slightly hyperactive, numbness or tingling or pins and needles (particularly in the hands and feet), difficulty in co-ordinating movements, fits
- **Effects on your liver:** 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)
- **Effects on your hormones:** change in sexual function and sex drive, breast swelling in men and women, production of breast milk, pain in the testicles, increased or decreased blood sugar levels, inappropriate secretion of the hormone ADH (antidiuretic hormone) that may make you pass water (urinate) more frequently.

Tell your doctor if you get any of these side effects:

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

- **Effects on your ears:** buzzing or ringing in the ears
- **Effects on your stomach and intestines:** feeling or being sick, nasty taste in your mouth, dry mouth, constipation, diarrhoea
- **Effects on the skin:** skin rashes, skin rash due to sunlight, swollen face, bleeding from the skin, swelling of the moist areas of the body such as the nose
- **Effects on your eyesight:** blurred or double vision, changes in eyesight, glaucoma
- **General effects:** headache, dizziness, tiredness, increased sweating, difficulty passing water, shaking.

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 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 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

- Keep this medicine out of the sight and reach of children.
- Store between 4°C and 25°C. Store away from direct light.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP: month year. The expiry date refers to the last day of that month.
- Do not use this medicine if you notice anything wrong with the medicine. Talk to your pharmacist.
- 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 contains

- The active ingredient is lofepramine hydrochloride.
- The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), propylene glycol (E1520), sodium ascorbate (E301), sorbitol solution 70% non-crystallising (E420), liquid maltitol (E965), ethanol, colloidal silicon dioxide, cherry flavour (contains propylene glycol) and purified water.

What Lofepramine looks like and contents of the pack

A white to pale yellow/orange suspension with a cherry odour.
It comes in a brown glass bottle holding 150ml of suspension.

Marketing Authorisation Holder

Essential Pharma Ltd, 8a Crabtree Road, Egham, Surrey, TW20 8RN, UK.

Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

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