

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
Lofepamine 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 Lofepamine

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 Lofepamine 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 Lofepamine 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 methyl dopa, 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.

Lofepamine with food, drink and alcohol

Do not drink alcohol whilst taking Lofepamine.

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 Lofepamine passes into breast milk.

Driving and using machines

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

Lofepamine 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.