How to take Lofepramine Tablets

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 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.

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.

Marketing Authorisation Holder

Accord Healthcare Limited
Sage House
319 Pinner Road
North Harrow
Middlesex
HA1 4HF
United Kingdom

Manufacturer

Accord, Barnstable, EX32 8NS, UK.

This leaflet was last revised in October 2018

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

Lofepramine Tablets

70mg x 56's (UK)

IDE No.: 50959615
Dimensions: 296x210 (Reel Fed)
Component: Leaflet for Blisters
Pharmacode: 4429
Date Sent: 04/10/18
Technologist: R.Wrey

Technical Approval

Item number: BBBA3124
Originator: R.Wrey
Oragniation Date: 05/10/18
Revision Date: 10/05/19

Supplier: Actavis UK

Colours

1. Black
2. White
3. Red
4. Blue
5. Green
6. Other

Non Printing Colours

1. Profile
2. No
3. Yes
4. Details

UK-Eire-Artwork-Support@accord-healthcare.com

* Please note that only Artwork Studio is permitted to make changes to the artwork.
No changes are permitted by any 3rd party other than added notes and mark ups for required changes.

296x210 Leaflet Reel Fed Bi Fold Profile (BST)
**Other medicines and Lofepramine 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. fluoxetine, fluvoxamine)
- 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, tranquillisers 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 Parkinsons disease, irritable bowel syndrome, bladder problems, asthma
- medicines to thin the blood (e.g. warfarin)
- antimalarials (e.g. halofantrine, chloroquine)
- medicines to treat certain mental illnesses (e.g. pimozide, 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)
- alprazolam (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 Lofepramine tablets if you are going to have an operation. Anaesthetics may react with Lofepramine Tablets.

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

**Lofepramine 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**

Lofepramine Tablets are not recommended if you are pregnant or breast feeding.

**Driving and using machines**

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

**Lofepramine Tablets contain 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.

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**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.

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**How to take Lofepramine 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.

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**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.

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