

Package leaflet: Information for the user
Gamanil 70mg film-coated tablets
 lofepramine (as hydrochloride)

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

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2. What you need to know before you take Gamanil
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1. What Gamanil is and what it is used for

Gamanil belongs to a group of medicines called tricyclic antidepressants.

Gamanil is used to treat symptoms of depression.

2. What you need to know before you take Gamanil

Do not take Gamanil if you:

- are allergic to lofepramine or any of the other ingredients of this medicine (listed in section 6)
- are allergic to other tricyclic antidepressants such as clomipramine and imipramine
- suffer from any mental illness other than depression (known as mania)
- have serious liver or kidney problems
- suffer from any serious heart problems, including irregular heart rhythms or have recently had a heart attack
- have untreated glaucoma (raised pressure of the fluid inside the eye)
- suffer from prostate problems with urinary retention
- suffer from chronic constipation
- are currently suffering from alcohol or drug poisoning or delirium
- are taking medicines to treat depression known as **monoamine oxidase inhibitors (MAOIs)** such as phenelzine and iproniazid or you have taken MAOIs within the last 14 days

Warnings and precautions

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

- have a history of, or you suffer from any heart, circulation, liver or kidney disorders
- suffer from blood disorders such as porphyria
- suffer from an overactive thyroid gland and are taking medicine to treat this condition
- have a history of epilepsy or recent convulsions (fits)
- are undergoing alcohol withdrawal
- suffer from chronic constipation, especially if you are elderly or bed-ridden
- have suffered from prostate problems
- have suffered from glaucoma (raised pressure of the fluid inside the eye)

- have an adrenal tumour for example phaeochromocytoma or neuroblastoma
- have any other mental illness (including a history of mania)
- are having electroconvulsive therapy for your depression
- know that you have high blood pressure (hypertension)

Important:

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 the anaesthetist or other medical staff that you are taking Gamanil.

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, 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 adults aged 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 might 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

Gamanil is not suitable for children and adolescents under 18 years of age.

Other medicines and Gamanil

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

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

- medicines used to treat disturbances of the heart rhythm such as disopyramide, procainamide, propafenone, sotalol, quinidine and amiodarone
- medicines that may interfere with the electrical conduction of the heart such as certain antibiotics, cisapride, anti-malarials, anti-histamines (to treat allergies) or neuroleptic drugs (medicines used to treat psychosis)
- other medicines used to treat depression including Serotonin Selective Reuptake Inhibitors (SSRIs) such as fluoxetine and fluvoxamine and other tricyclic anti-depressants, or drugs that control your moods or alprazolam which makes you feel less anxious
- medicines used to treat heart problems such as digoxin
- anticoagulants such as warfarin used to thin the blood
- calcium channel blockers such as diltiazem or verapamil or other medicines used to treat high blood pressure
- diuretics (water tablets)
- cough and cold remedies or other medicines containing phenylephrine or phenylpropanolamine
- medicines used to treat epilepsy including barbiturates such as phenobarbital
- medicines used to treat Parkinson's disease
- medicines that lower blood potassium levels used to treat high blood pressure or diuretics which are mainly used to treat heart failure
- rifampicin used to treat tuberculosis (TB)
- cimetidine - used to treat stomach acid problems or indigestion
- altretamine used to treat ovarian cancer

- disulfiram - used in the treatment of alcohol problems
- nitrates - used to treat angina
- ritonavir - used to treat HIV
- medicines to treat thyroid problems
- oral contraceptives
- medicines which make you feel sleepy or less alert; alcohol and general anaesthetic
- painkillers
- other anti-cholinergics used to treat Parkinson's disease, irritable bowel syndrome, bladder problems and asthma

Gamanil with alcohol

Do not drink alcohol whilst taking this medicine as it may affect you more than usual.

Pregnancy and breast-feeding

Gamanil is not recommended if you are pregnant or breast-feeding.

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

Driving and using machines

Gamanil is known to cause drowsiness, dizziness and visual problems especially at the start of treatment. If you suffer from these side effects, do not drive or operate machinery until you know how it will affect you.

Gamanil contains lactose and Cochineal Red (E124)

Gamanil contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine also contains Cochineal Red (E124), a colouring agent. This may cause allergic reactions.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take Gamanil

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

Dosage

Adults: The recommended dose is one tablet (70mg) to be taken two times a day. Your doctor may decide to increase this dose to three times a day.

Elderly patients: You may be prescribed a lower dose.

Use in children and adolescents

Gamanil is not suitable for children and adolescents under the age of 18.

Method of administration

Swallow the tablet whole with a glass of water. The score line is only there to help you break the tablet if you have difficulty swallowing it whole.

Duration of treatment

You should take your medicine for as long as your doctor says. Make sure that you do not run out of your tablets. You may need to take your medicine for some time before you begin to feel better. So do not stop taking this medicine because you think it is not working.

If you take more Gamanil than you should

If you (or someone else) have taken too many tablets, contact your doctor or go to your nearest hospital casualty department straight away. Take the container and any remaining tablets with you. You may experience drowsiness, restlessness, seizures or heart problems.

If you forget to take Gamanil

If you forget to take a dose, take it as soon as you remember, unless it is nearly time for your next dose, then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Gamanil

Do not suddenly stop taking your tablets without talking to your doctor first. It may be necessary to stop taking your medicine gradually.

This will help to avoid problems such as insomnia, irritability and excessive sweating.

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.

Contact your doctor or go to your nearest hospital immediately if you experience any of the following side effects:

- worsening of depression; if you have thoughts of harming or killing yourself at any time. (See section 2).
- 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 (soreness/inflammation of the mucosal membranes)
- your skin or eyes start turning yellow or you have severe stomach ache (you may have liver problems such as hepatitis or jaundice)
- feeling feverish or having chills, sore throat or sore tongue, ulcers in your mouth or throat, unusual tiredness or weakness (you may have a blood disorder)

The following side effects have also been reported. Tell your doctor immediately if you notice any of the following symptoms:

- low blood pressure which may be characterised by dizziness, fainting, nausea, feeling cold or clammy, confusion and anxiety
- interference with heart function such as fast heart rate or irregular heart rhythm
- dizziness, drowsiness, tremor, uncoordinated movements, convulsions (fits), impairment of the sense of taste
- disturbed sleep pattern, nightmares, hallucinations
- agitation, confusion, headache, malaise (feeling of general discomfort or uneasiness)
- nausea (feeling sick), vomiting (being sick) and diarrhoea, constipation, dryness of mouth
- facial swelling, sweating
- increased sensitivity to the effects of the sunlight
- pins and needles
- visual disturbances (such as blurred vision)
- glaucoma, (raised pressure of the fluid inside the eye)
- difficulty in urinating
- interference with sexual function, discomfort or pain in the testicles, enlargement or tenderness of the breast tissue in men, secretion of milk from the breasts
- mood swings
- tinnitus (ringing in the ears)
- low blood sodium levels and changes in blood sugar level.

Bone fractures: An increased risk of bone fractures has been observed in patients taking these types 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 HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Gamanil

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 carton and blister after “EXP”. The expiry date refers to the last day of that month.

Store below 25°C.

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

Do not use this medicine if you notice visible signs of deterioration.

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 Gamanil contains

The active substance is lofepramine (as lofepramine hydrochloride). Each tablet contains 76.10 mg lofepramine hydrochloride, equivalent to 70.0mg lofepramine.

The other ingredients are lactose monohydrate, maize starch, ascorbic acid, talc, glycerol 85%, glycerol monostearate 40-55, disodium edetate (Titriplex III), Dimeticone 1000, silica colloidal anhydrous (E551), hypromellose (HPMC 15). The coating contains macrogol 400, hypromellose (HPMC 5), hypromellose (HPMC 15), Cochineal Red (E124), talc, titanium dioxide (E171) and Indigotine Lake (E132).

What Gamanil looks like and contents of the pack

Gamanil 70mg film-coated tablets are violet with occasional white dots, round film coated tablets, biconvex on both sides with a dividing score on one side, approximately 10 mm in diameter.

The tablets come in PVC/PVDC/Al blister packs of 56 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Zentiva, k.s.,

U kabelovny 130, Dolní Měcholupy, 102 37 Prague 10, Czech Republic

Manufacturer

Prestige Promotion Verkaufsförderung und Werbeservice GmbH
Lindigstraße 6, 63801 Kleinostheim, Germany.

Or

P&G Health Austria GmbH & Co. OG,
A-9800 Spittal/Drau, Hosslgasse 20, Austria.

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