

PACKAGE LEAFLET: Information for the patient

LEVOMEPROMAZINE

Sugar-coated tablets – 25 mg

(Levomepromazine maleate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- 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.

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1. WHAT LEVOMEPROMAZINE IS AND WHAT IT IS USED FOR

Levomepromazine belongs to the group of phenothiazine neuroleptics.

It acts on hypothalamus, thalamus, reticular formation and on limbic system, inhibiting the sensory impulses.

Levomepromazine antagonizes dopamine D₂ receptors, 5HT₃-serotonin receptors, histamine H₁ receptors, and cholinergic (muscarinic) receptors.

As a result of this antagonism appears a calming effect in small doses, an antipsychotic effect in high doses, as well as increase of the threshold of pain and stimulation of amnesia.

Levomepromazine also has analgesic, antihistaminic and anticholinergic effect.

This medicine does not cause respiratory depression, therefore it is useful especially in patients with low respiratory reserve.

Levomepromazine is used in the treatment of:

- psychoses, to control agitation and psychomotor agitation in moderately severe depression;
- schizophrenia;
- psychotic disorders with hallucinations;
- personality disorders in patients with epilepsy;
- neurotic disorders;
- as an analgesic to relieve moderate to severe pain prior to surgery;
- incoercible vomiting.

2. BEFORE YOU TAKE LEVOMEPROMAZINE

Do not take Levomepromazine if:

- you are allergic (hypersensitive) to levomepromazine maleate or to any of the excipients listed at the end of this leaflet;
- you are hypersensitive to the phenothiazines group;
- you are in comatose state;
- you suffer from severe liver disease;
- you suffer from severe renal disease;
- you suffer from severe myocardial disorders;
- you suffer from severe hypotension;
- you suffer from pheochromocytoma;
- you suffer from CNS depression;
- you have suppression of the bone marrow.

Take special care with Levomepromazine

Tell your doctor before starting to take Levomepromazine.

Special care is required in children, elderly and during pregnancy.

Blood tests and tests of the liver function should be done if long-term treatment with levomepromazine is needed.

The drug may cause sleepiness, disorientation, confusion, low blood pressure, which may damage the ability of the patient to drive and operate machinery.

Patients over 50 years old are at an increased risk for hypotension.

Alcohol should be avoided during the treatment period.

Levomepromazine should be used with caution in patients with glaucoma and prostatic hypertrophy because this drug causes antimuscarinic effects.

Levomepromazine should be used with caution in patients with cardiovascular, cerebrovascular and respiratory disease, Parkinson's disease, epilepsy, in the presence of acute infections and leukopenia, in hyperthyroidism, in patients with a history of jaundice and myasthenia gravis.

Levomepromazine should be used with caution in patients who suffer from slow or irregular heartbeats / palpitations (Torsades de Pointes), or have a family history of heart problems.

Talk to your doctor or pharmacist if you or someone else in your family have a history of blood clots, as medicines like these have been associated with formation of blood clots.

Levomepromazine should be used with caution in patients who are diabetic or have been told that have an increased risk of having diabetes or already know that have low levels of potassium, calcium or magnesium in their blood.

At high doses, light sensitivity can occur, so direct exposure to the sun should be avoided.

Take caution using this drug in patients who suffer from dementia and are elderly.

Antipsychotic drugs should not be used in elderly patients to treat mild to moderate psychotic symptoms. Initial doses of antipsychotic drugs in elderly patients should be reduced (half the adult dose or less) taking into account factors such as the patient's weight, co-morbidity and concomitant medication. Treatment should be reviewed regularly.

Taking other medicines

Concomitant treatment with other medicines may affect or be affected by Levomepromazine. Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Do not forget to inform your doctor about the treatment with Levomepromazine if you receive any other medicines during treatment.

It is especially important that your doctor should be informed about the fact that you have been

treated with one of the following drugs:

- phenothiazines and other central nervous system inhibitors (general anaesthetics, alcohol, antihistamines, barbiturates, narcotics, tranquillisers) because levomepromazine enhances their effect, that's why the doses of these medicines should be halved if used concomitantly with levomepromazine;
- antimuscarinics, myorelaxants, phosphoroorganic insecticides, because the medicine can increase their effect;
- medicines that prolong QT interval;
- medicines that cause electrolyte imbalance;
- antihypertensive drugs; the effect of guanethidine and other similar drugs can be antagonised;
- clonidine, because levomepromazine can strengthen its hypotensive effect and its central effect;
- amiodarone, dronedarone, moxifloxacin, citalopram, escitalopram, piperaquine with artemimol, pimozide, saquinavir, the risk for ventricular arrhythmia is increased; they should not be used at the same time;
- disopyramide, ritonavir, sotalol, pentamidine isethionate;
- propranolol, because it reduces the hepatic metabolism of phenothiazines, while the latter reduce the hepatic metabolism of propranolol;
- drugs that block the dopaminergic receptors in the CNS such as droperidol, haloperidol, metoclopramide, olanzapine, risperidone;
- antiepileptic drugs, because antipsychotic drugs antagonise their anticonvulsant effect;
- lithium, because the risk for extrapyramidal symptoms and neurotoxicity is increased;
- artemether with lumefantrine, desferrioxamine, the simultaneous use should be avoided;
- adrenaline and other adrenergic agonists;
- antiparkinsonian drugs such as levodopa, pergolide, pramipexole and ropinirole;
- antiacids, because they decrease the absorption of levomepromazine;
- oral contraceptives, quinolones, sulphonamides, sulfonylureas, tetracyclines, thiazide diuretics, vitamine A analogues, because the simultaneous use with phenothiazines increases the sensitivity to light of these medicines.

Taking Levomepromazine with food and drinks

Levomepromazine should not be taken with alcohol.

Pregnancy

Ask your pharmacist or doctor for advice before taking this medicine.

Levomepromazine should not be used during pregnancy, unless the doctor deems it necessary and the benefit / risk factor is measured.

Therefore, always consult your doctor before using Levomepromazine during pregnancy.

Breastfeeding

Levomepromazine is excreted into breast milk and therefore should not be used during breastfeeding.

Driving and using machines

Levomepromazine can cause drowsiness, disorientation, confusion and significant hypotension, which may affect the ability of the patient to drive or use machinery.

Important information about some of the excipients of Levomepromazine

This medicine contains lactose and sucrose. If you have been told by your doctor that you have an intolerance to some sugars, you should contact your doctor before taking Levomepromazine.

This drug contains sodium benzoate.

3. HOW TO TAKE LEVOMEPRAMAZINE

Always take Levomepromazine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Levomepromazine are too strong or too weak, talk to your doctor or pharmacist.

The tablets should be swallowed with at least half glass of water.

You can take them before or after food.

Dosage varies according to the indication and the objective sought to be achieved. Generally, treatment is advisable to start with low doses that are gradually increased until the optimal dose.

Schizophrenia treatment:

12.5 - 50 mg daily in 3-4 divided doses. Bedpatients may take 100 - 200 mg daily, usually in 3 – 4 divided doses, increased if necessary to 1 g daily.

However, doses may need to be increased or to be decreased. Your doctor will advise you accordingly.

If you take more Levomepromazine than you should

If you take more Levomepromazine than you should, or if the children take it accidentally, please contact your doctor immediately, the local hospital, or any medical care site to seek advice on the risk and the appropriate measures.

Symptoms of overdose are similar to the symptoms of parkinsonism.

If you forget to take Levomepromazine

If you forget to take a dose (or more than a dose), take the next dose at its usual time. Do not take a double dose (or higher) to make up for the forgotten dose(s).

If you stop taking Levomepromazine

Avoid abrupt withdrawal!

Reduction of the dosage should be gradual.

If you have further questions on the use of this medicinal product, please contact your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, levomepromazine can cause side effects, although not everybody gets them. Sometimes they are serious, sometimes not.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

The possible side effects are shown below:

- sleepiness and asthenia;
- sometimes dry mouth may occur.

In elderly patients it can cause hypotension. Tachycardia, alteration of heart rhythm (called ‘prolongation of QT interval’ seen on ECG, electrical activity of the heart), extrapyramidal

symptoms, agranulocytosis and leucopenia have been noticed.

In patients treated for a long period of time and with high doses, reactions similar to parkinsonism can appear.

Other side effects include being tired, weakness, confusion, have muscles that ache, are stiff (this may be due to low sodium levels in your blood), heat stroke, blurred vision, accommodation disorders, pigmentary retinopathy, high temperature, sweating, pale complexion, dizziness, feeling faint or loss of alertness.

Levomepromazine can cause constipation, which may become severe and stop food moving through the bowel, colicky abdominal pain with bloody diarrhoea.

In vascular system can cause blood clots in the veins especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. Venous thromboembolism, pulmonary embolism, sometimes fatal and cases of deep vein thrombosis have been reported with antipsychotic drugs. A serious but rare side effect is neuroleptic malignant syndrome. Signs of this include a high fever, sweating, stiff muscles, fast heart rate, fast breathing and drowsiness or confusion. There may also be difficulty in walking and shaking or involuntary muscle movements. Rarely there may be rolling of the eyes.

If these symptoms develop please contact your doctor immediately.

Levomepromazine can cause jaundice (yellowing of the skin and eyes), an illness where the removal of bile from the liver is blocked (cholestasis) which include signs like jaundice, rash or fever, and the colour of your water (urine) becomes darker, or an infection or injury to the liver where the patient has discolouration of the skin or eyes, pain in the abdomen (stomach) or a bloated feeling, severe itching, pale or bloody stools, extreme weakness, nausea or loss of appetite.

A syndrome of inappropriate antidiuretic secretion (SIADH) may appear after the use of this drug. Symptoms include feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable.

A syndrome resembling systemic lupus erythematosus has been reported.

Hyperglycaemia, glucose intolerance and in some cases increase of erythro sedimentation can occur.

Other side effects that are usual for phenothiazines neuroleptics can occur.

Levomepromazine has antimuscarinic properties and may cause adverse effects such as difficulty with micturition.

Haemolytic anemia, aplastic anaemia, thrombocytopenic purpura, eosinophilia, have been reported. They may be manifestations of a hypersensitivity reaction. Hypersensitivity reactions include, urticaria, erythema multiforme, contact sensitivity and dermatitis allergic.

Other adverse effects include rarely catatonic – like states, nightmares, depression, nasal congestion, inhibition of ejaculation, impotence, persistent and unwanted erection, amenorrhoea, galactorrhea, gynecomastia due to hyperprolactinemia, drug withdrawal syndrome neonatal, skin irritation or burning due to sensitivity to sunlight and weight gain.

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

5. HOW TO STORE LEVOMEPRAMAZINE

Keep out of the reach and sight of children!

Do not use Levomepramazine after the expiry date, stated on the package.

Do not store above 25°C.

Keep in the original package to protect from light.

6. FURTHER INFORMATION

What Levomepramazine sugar-coated tablets contain

The active substance is levomepramazine maleate.

Each sugar-coated tablet contains 25 mg levomepramazine maleate.

The excipients are: maize starch, lactose monohydrate, povidone, magnesium stearate, talc, gelatin, calcium carbonate, titanium dioxide, sucrose, quinoline yellow, indigo carmine, sodium benzoate, shellac, carnauba wax, beeswax white.

Content of the pack

Box with 30 sugar-coated tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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