PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Levomepromazine Maleate

6mg Tablets

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

1. What Levomepromazine Maleate Tablets are and what they are used for

Levomepromazine is a phenothiazine used in palliative care and indicated for second or third line-treatment of adults with refractory nausea unassociated with chemotherapy, where other agents have failed to give adequate control (CCC System - B62.1 Nausea Care).

2. What you need to know before you take Levomepromazine Maleate Tablets

Do not take Levomepromazine Maleate Tablets:
- if you are allergic to levomepromazine maleate or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions:
Talk to your doctor or pharmacist before taking Levomepromazine Maleate Tablets if you:
- have liver problems
- are elderly, frail or have heart disease as you may feel faint or light-headed when you take the tablets (if you have a large initial dose, you will have to stay in bed)
- suffer from slow or irregular heartbeats/ palpitations (Torsades de Pointes), or have a family history of heart problems
- or someone else in your family have a history of blood clots, as medicines like these have been associated with formation of blood clots
- suffer from dementia and are elderly
- have been told by your doctor that you might have a stroke
- are diabetic or have been told you have an increased risk of having diabetes
- already know you have low levels of potassium, calcium or magnesium in your blood
- find it difficult, or are unable, to eat
- are an alcoholic
- have epilepsy

Additional tests will be done by your doctor at the start of treatment if you are taking Levomepromazine Maleate Tablets for a long period of time, or if you are taking other medicines at the same time such as heart drugs, antidepressants or drugs for mental health disorders.

These tests might include an ECG (electrocardiogram) to check your heart is working normally and/or blood tests. If you have to go to the dentist or hospital for any reason, tell them that you are taking Levomepromazine Maleate Tablets.

Other medicines and Levomepromazine Maleate Tablets
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including those obtained without a prescription, as they may change the way Levomepromazine Maleate Tablets work.

These include:
- medicines for the treatment of irregular heartbeats
- antidepressants such as amitriptyline and amitriptylinoxide and drugs for other mental health disorders (i.e. antipsychotics)
- desferrioxamine (for iron poisoning)
- adrenaline (epinephrine) in patients overdosed with antipsychotic drugs.

Levomepromazine Maleate Tablets with alcohol
Avoid alcohol while you are taking these tablets.

Pregnancy, breast-feeding and fertility
If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist before taking Levomepromazine Maleate Tablets or any other medicine.
The following symptoms may occur in newborn babies, of mothers that have used Levomepromazine Maleate Tablets in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines
Do not drive or operate machinery if taking Levomepromazine Maleate Tablets as they may make you feel drowsy, confused, dizzy or lightheaded.

Levomepromazine Maleate Tablets contain lactose
This medicine contains lactose, which is a sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Levomepromazine Maleate Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The tablets should be swallowed with a glass of water.

The recommended dose is as follows:

Adults:
Nausea in palliative care.
Your doctor will review your treatment on a daily basis.

Number of days of treatment	Number of tablets
Initial (3 days)	½ to 1 tablet to be taken once at night for 3 days.
4 to 5 days	Your dose may be increased up to maximum of 2 tablets on days 4-5. This may be achieved by taking 1 tablet twice a day.
6 to 14 days	From day 6 the dose may then be switched to 2 tablets once daily at night, or as directed by your doctor. Your treatment may be extended to a maximum of 2 weeks, as needed.

Use in children and adolescents
No data are available. Levomepromazine tablets should not be used in children aged under 18 years.

Method of administration
For oral use only.
The tablet can be divided into equal doses.

If you take more Levomepromazine Maleate Tablets than you should
If you accidentally swallow too many tablets, contact your doctor or nearest hospital casualty department immediately.

Symptoms of overdose include: drowsiness or loss of consciousness, convulsions, low blood pressure, irregular heartbeats, hypothermia (abnormally low body temperature) and severe extrapyramidal dyskinesias (involuntary movements).

If you forget to take Levomepromazine Maleate Tablets
If you miss a dose, just take your tablets as soon as you remember then carry on as before. Do not take a double dose to make up for the forgotten one. If you have any further questions on the use of this product, ask your doctor or pharmacist.

If you stop taking Levomepromazine Maleate Tablets
Do not stop taking Levomepromazine Maleate Tablets unless your doctor tells you to.

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.

No formal reporting has been made about the undesirable effects of low-dose levomepromazine formulations; therefore, adverse effects cannot be ranked by frequency. Most available data on adverse effects are related to application of higher doses, i.e., ≥ 25 mg. Adverse effects that are more frequent and indicate the need for medical attention are as follows:

- Dystonic extrapyramidal effects (spasms of eye, face, neck and back muscles)
- Akathisia (motor restlessness)
- Hypotension
- Ocular changes including deposition of opaque material in lens and cornea, epithelial keratopathy or pigmentary retinopathy (blurred vision; defective colour vision; difficulty seeing at night)
- Parkinsonism-like extrapyramidal effects (rigidity and tremor)
- Tardive dyskinesia (unusual facial expressions or body positions, increased blinking or spasms of eyelid, uncontrolled twisting movements of neck, trunk, arms, or legs).

Hypotension is more frequent in the elderly and at the beginning of treatment, especially if high doses are used. Parkinsonian effects and tardive dyskinesia also occur more frequently in the elderly, whereas dystonia occurs more often in younger patients. Extrapyramidal effects may be dose-related and may decrease with a decrease in dosage. Ocular changes occur more frequently with high-dose or long-term use of phenothiazines.

Less frequent AEs include difficulty in urinating, photosensitivity (may cause severe sunburn), skin rash associated with contact dermatitis or cholestatic jaundice.
With rare incidence the following AEs may occur:

- Blood dyscrasias including agranulocytosis leukocytopenia or thrombocytopenia (Agranulocytosis can develop within the first 3 months of treatment, with recovery within 1 to 2 weeks after medication is discontinued; it may recur upon rechallenge in recovered patients.)
- Melanosis (Skin pigmentation changes in melanosis occur on exposed areas of the body and may fade after discontinuation of the drug.)
- Neuroleptic malignant syndrome (NMS may occur at any time during neuroleptic therapy and is potentially fatal. It is most commonly seen within the first month of therapy, after the patient has switched from one neuroleptic to another, or after a dosage increase.)
- Obstipation or paralytic ileus
- QT prolongation and torsades de pointes
- Seizures
- Dark urine (Dark urine usually is caused by the presence of phenothiazine metabolites in the urine.)
- Significant fever, and temperature regulation dysfunction. (Significant fever not attributable to any other cause may represent an idiosyncratic reaction. Levomepromazine may cause hypothermia in cold weather, since the disruption of the thermoregulatory mechanisms results in a poikilothermic state. Heatstroke caused by phenothiazine-induced suppression of temperature regulation in the hypothalamus may occur in environmental conditions of high heat and high humidity).
- Jaundice may appear about 2 weeks after severe pruritus and may progress to chronic active hepatitis.

In the only double blind, randomised, controlled trial of low-dose levomepromazine (6.25mg once or twice daily), the most frequent side effects were

- Drowsiness (20.4%)
- Fatigue (16.3%)
- Constipation (12.2%)
- Headache, hypotension, and dry mouth (each 8.2%).

Additional side effects included dyspepsia, hypertension, diarrhoea, bruising (each 6.1%), dizziness, bowel colic, blurred vision (each 4.1%), confusion, sensitivity to light, palpitations, and jaundice (each 2.0%). Side effects worse than baseline were minimal, specifically those relating to extrapyramidal reactions.

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

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 Yellow Card Scheme at: 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 Levomepromazine Maleate Tablets

Keep this medicine out of the sight and reach of children.

This medicinal product does not require any special temperature storage conditions. Store in the original package in order to protect from light.

Do not use this medicine after the expiry date which is stated on the carton or blister after 'EXP'.The expiry date refers to the last day of that month.

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 Levomepromazine Maleate Tablets contain

- The active substance is Levomepromazine Maleate, 6mg per tablet.
- The other excipients are: lactose monohydrate, pregelatinized maize starch, povidone K-29/32, silica colloidal anhydrous, magnesium stearate.

What Levomepromazine Maleate Tablets look like and contents of the pack
The tablets are white to off white round shaped tablet with break line on one side and 'L4' debossing on another side. The tablet can be divided into equal halves.

They are supplied in blister packs of 7, 10, 14, 20, 24, 28, 30, 56, 60, 84, 90, 100 and 112 tablets.

Not all pack sizes may be marketed.

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This leaflet was last revised in March 2020.

M0334LAMUKNA-S-001