Package leaflet: Information for the patient
Levorol 6.25 mg and 25 mg Tablets

Levomepromazine maleate

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.

The name of your medicine is Levorol 6.25 mg or 25 mg Tablets, but it will be referred to as Levorol Tablets throughout this leaflet.

What is in this leaflet

1. What Levorol Tablets are and what they are used for

Levorol Tablets is a medicine that contains the active substance levomepromazine maleate. Levorol Tablets belong to a group of medicines called phenothiazines and are used:
- in schizophrenia
- in the relief of pain and the accompanying distress in terminally ill patients
- as secondary treatment for adults with refractory nausea unassociated with chemotherapy who have not responded to standard treatment.

2. What you need to know before you take Levorol Tablets

Do not take Levorol Tablets
- If you are allergic (hypersensitive) 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 Levorol 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 Levorol 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 Levorol Tablets.

Other medicines and Levorol Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
These include:
- medicines for the treatment of irregular heartbeats
- antidepressants such as amitriptyline, amitriptylinoxide and nortriptyline and drugs for mental health disorders (i.e. antipsychotics)
- desferrioxamine (for iron poisoning)
- adrenaline (epinephrine) in patients overdosed with antipsychotic drugs.

Levorol Tablets with alcohol
Avoid alcohol while you are taking these tablets.

Pregnancy and 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. The following symptoms may occur in newborn babies, of mothers who have used Levorol 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 Levorol Tablets as they may make you feel drowsy, confused, dizzy or lightheaded.

Levorol 6.25 mg Tablets and Levorol 25 mg Tablets contain sodium.
These medicines contain less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Levorol Tablets

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

The recommended dose is as follows:

Schizophrenia
Adults
The initial dose is usually 25 mg to 50 mg a day, divided into three doses. If you are confined to bed, the initial dose may be 100 mg to 200 mg a day, divided into three doses. These doses may be increased in small steps until a suitable dose is found for you.

Elderly
Your doctor will decide whether these tablets are appropriate for you and will tell you how many to take.

Pain management
Adults and elderly
12.5 mg to 50 mg every four to eight hours; the dose may be varied until a suitable dose is found for you.

Refractory nausea unassociated with chemotherapy
Adults and elderly
Your doctor will review your treatment on a daily basis.

6.25 mg once daily, taken at bedtime, increased -if necessary- to 12.5-25 mg twice daily.

Use in children and adolescents
Schizophrenia
Normally no more than 37.5 mg (1½ tablets of Levorol 25 mg tablets) a day.

Pain management
Levorol Tablets should not be used in children aged under 18 years.

Refractory nausea unassociated with chemotherapy
Levorol Tablets should not be used in children aged under 18 years.

Use in patients with kidney problems
Smaller initial doses are recommended.

Method of administration
For oral use only.

The tablets should be swallowed with a glass of water.

The tablets can be divided into equal doses.

If you take more Levorol Tablets than you should
If you, or a child, 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 Levorol 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 Levorol Tablets
Do not stop taking Levorol 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.

STOP taking the tablets and SEEK medical help immediately if you have any of the following allergic reactions:
- difficulty breathing or swallowing, swelling of the face, lips, tongue or throat
- severe itching of the skin, with a red rash or raised lumps.

Tell your doctor IMMEDIATELY if you experience any of the following:
Common: may affect up to 1 in 10 people:
- low blood pressure, especially in elderly patients
- heat stroke
- alteration of heart rhythm (called 'prolongation of QT interval' seen on ECG, electrical activity of the heart)

Uncommon: may affect up to 1 in 100 people:
- stiffness, shaking (tremor) or slow movements
- you have a fit (seizure)
- blood abnormalities
- constipation, which may become severe and stop food moving through the bowel

Rare: may affect up to 1 in 1,000 people:
- heart palpitations (usually rapid or irregular heartbeats)
- jaundice (yellowing of the skin and eyes)

Not known: frequency cannot be estimated from the available data:
- dizziness, feeling faint or loss of alertness
- 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. **If you notice any of these symptoms seek medical advice immediately**
- 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**.
- high temperature, sweating, pale complexion, difficulty passing urine
- colicky abdominal pain with bloody diarrhoea
- skin irritation or burning due to sensitivity to sunlight
- unwanted and persistent erections
- an illness where the removal of bile from

the liver is blocked (cholestasis). Signs include jaundice, rash or fever, and the colour of your water (urine) becomes darker
- 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. This could be caused by an infection or injury to the liver
- tired, weak, confused, have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood
- feeling unwell, confused and/or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be something called a syndrome of inappropriate antidiuretic secretion (SIADH)

Other side effects include:

If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.
Very common: may affect more than 1 in 10 people:
- sleepiness
- dry mouth

Common: may affect up to 1 in 10 people:
- weakness

Not known: frequency cannot be estimated from the available data:
- high blood sugar (hyperglycaemia)
- feeling confused

A small increase in the number of deaths has been reported in elderly patients with dementia who are taking antipsychotics compared with those not taking antipsychotics.

Most available data on adverse effects are related to application of higher doses, i.e., ≥ 25 mg.

No formal reporting has been made about the undesirable effects of low-dose levomepromazine formulations; therefore, adverse effects cannot be ranked by frequency.

In the only double blind, randomised, controlled trial of low-dose levomepromazine (6.25 mg 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.

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:

Website: 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 Levorol Tablets

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 in the original package in order to protect from light.

This medicine does not require any special temperature storage conditions.

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 Levorol Tablets contains
Levorol 6.25 mg Tablets
- Each tablet contains 6.25 mg of the active substance levomepromazine maleate.
- The other ingredients are starch pregelatinised, calcium hydrogen phosphate (E341), sodium laurilsulfate (E487) and magnesium stearate (E572).

Levorol 25 mg Tablets
- Each tablet contains 25 mg of the active substance levomepromazine maleate.
- The other ingredients are starch pregelatinised, calcium hydrogen phosphate (E341), sodium laurilsulfate (E487) and magnesium stearate (E572).

What Levorol Tablets look like and contents of the pack
Levorol 6.25 mg Tablets
Levorol 6.25 mg Tablets are white, flat, round tablets of approximately 6 mm diameter scored on one side.

PVC/PVDC/aluminium blisters.

Pack size: 28 tablets.

Levorol 25 mg Tablets
Levorol 25 mg Tablets are white, biconvex, round tablets of approximately 10 mm diameter scored on one side.

PVC/PVDC/aluminium blisters.

Pack size: 84 tablets.

Marketing Authorisation Holder and Manufacturer

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