PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

MORNINGSIDE HEALTHCARE

Levomepromazine Maleate

25 mg, 50 mg and 100 mg 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
2. What you need to know before you take Levomepromazine Maleate Tablets
3. How to take Levomepromazine Maleate Tablets
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1. What Levomepromazine Maleate Tablets are and what it is used for

Levomepromazine Maleate tablets belong to a group of medicines called phenothiazines and are used for:
- schizophrenia
- the relief of pain and accompanying distress in terminally ill patients.

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

Do not take Levomepromazine Maleate Tablets:
- if you are allergic (hypersensitive) to levomepromazine maleate or any of the other ingredients of this medicine (listed in section 6).
  Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- If you are taking any of the following medicines:
  - citalopram and escitalopram
  - hydroxyzine
  - piperaquine
  - domperidone

Warnings and precautions:
Talk to your doctor or pharmacist before taking Levomepromazine Maleate Tablets if :
- You have liver problems.
- You are an elderly patient with dementia.
- You are elderly, frail or have heart disease or you have had problems with dizziness or feeling faint when going from a lying or sitting to a standing position due to low blood pressure, 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. You should not get up quickly and you should obtain assistance when necessary.
- You suffer from slow or irregular heartbeats/ palpitations (Torsades de Pointes), or have a family history of heart problems.
- 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.
- You have been told by your doctor that you might have a stroke or you have risk factors (e.g. if you smoke or have high blood pressure, or have an excessive amount of sugar, cholesterol or fat in the blood). This medicine should be used with caution as the risk of a stroke (cerebrovascular accident) may be increased.
- You are diabetic or have been told you have an increased risk of having diabetes. You will need to monitor your blood sugar levels very carefully.
- You already know you have low levels of potassium, calcium or magnesium in your blood.
- You have constipation.
- You find it difficult, or are unable, to eat.
- You are an alcoholic.
- You have ever had convulsions or epilepsy.
- Your prostate (sperm-producing gland) has increased in size (prostate hypertrophy).
- You have an adrenal gland tumour (phaeochromocytoma).
- You have decreased thyroid hormone secretion condition (hypothyroidism).
- You have a muscle disease causing drooping eyelids, double vision, difficulty in speaking and swallowing and sometimes muscle weakness in the arms or legs (myasthenia gravis).

During the treatment
You must tell your doctor or nurse immediately if:
- You experience stiffness in your muscles, impaired consciousness and fever (see section 4).
- You have a fever, pallor, heavy sweating or any other sign of infection. In very rare cases, this medicine can cause a drop in your white blood cells which predisposes you to infection (see section 4).
- You have long-term constipation, as well as bloating and stomach pain, or a blocked intestine (Paralytic ileus) (see section 4).

Tests
Additional tests will be done by your doctor before and during treatment if you are taking Levomepromazine Maleate Tablets for a long period of time. This includes if you are taking other medicines at the same time such as heart drugs, anti-depressants or drugs for mental health disorders. Your doctor may carry out:
- blood tests to monitor your liver function
- blood tests to check your white blood cells due to a potential side effect, a significant decrease in the number of certain white blood cells in the blood (agranulocytosis)
- an ECG (electrocardiogram) to check your heart is working normally, as certain medicines in the same family as Levomepromazine Maleate Tablets (antipsychotics) can, in very rare cases, cause heart rhythm disorders (see section 4).

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

Do not take Levomepromazine Maleate Tablets and tell your doctor or pharmacist if you are taking any of the following medicines (see section 2 'Do not take Levomepromazine Maleate Tablets if'):
- citalopram and escitalopram – used to treat anxiety or depression
- hydroxyzine – used to treat the minor symptoms of anxiety, as premedication before general anaesthesia, in nettle rash and in the treatment of some kinds of insomnia
- piperaquine – used to treat malaria, an illness caused by a parasite
- domperidone – used to treat nausea and vomiting.

Before taking Levomepromazine Maleate Tablets, tell your doctor or pharmacist if you are taking any of the following medicines:
- medicines used for the treatment of Parkinson's disease
- cabergoline, quinagolide – used to treat the production of excessive or abnormal amounts of milk
- medicines containing alcohol
- desferrioxamine – used to treat iron poisoning
- adrenaline (epinephrine) – used to treat patients overdosed with antipsychotic drugs
- medicines that can cause severe heart rhythm disorders (torsades de pointes):
  - antiarrhythmics used to treat irregular heartbeats (e.g. amiodarone, dronedarone, disopyramide, hydroquinidine, quinidine and sotalol)
  - medicines used to treat mental health disorders such as anti-depressants (e.g. amitriptyline, amitriptylinoxide and nortriptyline) and antipsychotics (e.g. other neuroleptics or lithium-containing medicines)
  - sedatives and medicines used to treat anxiety (e.g. barbiturates)
  - anti-parasitics used to treat diseases caused by parasites (e.g. chloroquine, halofantrine, hydroxychloroquine, lumefantrine and pentamidine)
  - antibiotics used to treat infections (e.g. erythromycin and spiramycin administered into a vein, and moxifloxacin)
  - mizolastine – used to treat an allergy
  - anti-cancer medicines used to treat cancer (e.g. toremifene, arsenic trioxide and vandetanib)
  - dolasetron administered into a vein – used in adults to treat or prevent nausea and vomiting induced by some treatments or surgery
  - vincamine administered into a vein – used to treat some minor neurological disorders related to ageing
  - diphemanil – used to treat gastric secretion disorders and excessive perspiration
  - prucalopride – used to treat constipation
  - mequitazine – used to treat allergic rhinitis or hives
  - methadone – used to treat addiction.

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

Pregnancy and breast-feeding

Pregnancy:
Talk to your doctor or nurse before using this medicine:
- if you are a woman of childbearing potential and are not using effective contraception
- if you are pregnant, think you may be pregnant or are planning a pregnancy.

This medicine will only be used during pregnancy on the advice of your doctor.

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.

Breast-feeding
This medicine is excreted into breast milk. Breastfeeding is not recommended for the duration of treatment with this medicine.

Fertility
The use of this medicine can result in an excessive amount of prolactin (the hormone which causes milk to be produced) in the blood. This may be associated with a lowering of fertility.
If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor, nurse or pharmacist before taking any medicine.

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 or pharmacist if you are not sure. The tablets should be swallowed whole with a glass of water.

Levomepromazine Maleate Tablets are taken by mouth. The tablet can be divided into equal halves.

The recommended dose is as follows:

Schizophrenia
Adults - the initial dose is usually 1-2 tablets a day, divided into three doses. If you are confined to bed, the initial dose may be 4-8 tablets 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.
Children - will normally be given no more than 1½ tablets a day.

Pain management
Adults and Elderly – ½ to 2 tablets every four to eight hours; the dose may be varied until a suitable dose is found for you.
Children - these tablets are NOT recommended for children for treating pain.

If you take more Levomepromazine Maleate 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 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

STOP taking the tablets and tell your doctor or pharmacist IMMEDIATELY if you notice any of the following serious side effects – you may need urgent medical treatment:
- You have an **allergic reaction**. The signs include: severe itching of the skin, with a red rash or raised lumps (hives), difficulty breathing or swallowing, swelling of the face, lips, tongue or throat.

Common (may affect up to 1 in 10 people)
- low blood pressure, especially in elderly patients or when you move suddenly from lying or sitting to a standing position
- heat stroke.

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
- a significant decrease in the number of white blood cells, sometimes revealed by fever and breathing difficulties (agranulocytosis).

Rare (may affect up to 1 in 1,000 people)
- heart palpitations (usually rapid or irregular heartbeats)
- alteration of heart rhythm (called 'prolongation of QT interval' seen on ECG, electrical activity of the heart), which may, in exceptional cases, be life-threatening
- 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
- Neuroleptic malignant syndrome. Signs 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. **See also section 2**
- very severe inflammation of the intestine, which may cause localised destruction (necrosis), colicky abdominal pain with bloody diarrhoea
- skin irritation or burning due to sensitivity to sunlight
- unwanted, painful 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
- you have 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)
- disease of the brain (Parkinson's disease) affecting movement (trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk)
- uncontrollable twitching or jerking movements of the arms and legs (dyskinesia)
- decreased number of white blood cells (leukocytopenia), which may lead to serious infections.

Other side effects include:
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)
- lack of periods in women, increased breast size or breast growth in men, impotence, abnormal milk production
- high blood sugar (hyperglycaemia)
- a change in body temperature
- mood disorders, feeling anxious or confused
- weight gain
- vision problems including disorders affecting the ability of your eyes to adapt to see close up or far away (accommodation disorders), or brownish deposits in the eye that do not generally affect vision.

In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

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, pharmacist or nurse. 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
  Each 25mg tablet contains 25mg Levomepromazine Maleate
  Each 50mg tablet contains 50mg Levomepromazine Maleate
  Each 100mg tablet contains 100mg Levomepromazine Maleate

- 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
Levomepromazine Maleate 25mg Tablets are white to off white round shaped tablet with break line on one side and 'L3' debossing on another side.
Levomepromazine Maleate 50mg Tablets are white to off white round shaped tablet with break line on one side and 'L2' debossing on another side.
Levomepromazine Maleate 100mg Tablets are white to off white round shaped tablet with break line on one side and 'L1' debossing on another side.

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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