

# Levomepromazine Maleate

25mg, 50mg and 100mg 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 is and what it is 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 is 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).

#### 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 nortriptyline and drugs for other mental health disorders (i.e. antipsychotics)
- desferrioxamine (for iron poisoning)
- adrenaline (epinephrine) in patients overdosed with antipsychotic drugs.

#### Taking with food and drink

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; you should check with him/her 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 25mg to 50mg a day, divided into three doses. If you are confined to bed, the initial dose may be 100mg to 200mg 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 37.5mg a day.

#### Pain management

*Adults and Elderly* – 12.5mg to 50mg 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.

**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.

**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.

Very common: may affect more than 1 in 10 people:

- sleepiness
- dry mouth

Common: may affect up to 1 in 10 people:

- weakness

**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
- 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)

Other side effects include:

Not known: frequency cannot be estimated from the available data:

- high blood sugar (hyperglycaemia)
- feeling confused

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 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](http://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.

**Marketing Authorisation Holder**

Morningside Healthcare Limited  
Unit C, Harcourt Way  
Leicester, LE19 1WP  
United Kingdom

**Manufacturer**

Morningside Pharmaceuticals Ltd.  
5 Pavilion Way  
Loughborough, LE11 5GW  
United Kingdom

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