Levomepromazine Maleate Tablets

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.
• 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 heart problems — e.g. you have had a heart attack, have had a heart valve replaced, have an abnormal heart rhythm, have had a heart operation or have had a blood clot in your blood vessels, have a family history of heart problems
• have diabetes
• are elderly
• have a stroke
• have a condition which affects your liver, or are taking any medicine that affects your liver
• have kidney problems
• have a condition in which there is a risk of bleeding
• suffer from a number of blood disorders
• have a low white blood cell count
• have a blood disorder
• have a low platelet count
• have a blood clotting disorder
• have had a blood disorder

• 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
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2. What you need to know before you take Levomepromazine Maleate Tablets
3. How to take Levomepromazine Maleate Tablets
4. Possible side effects
5. How to store Levomepromazine Maleate Tablets
6. Contents of the pack and other information

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).

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:

Adults: the initial dose is usually 25mg to 50mg every four to six hours; the dose may be varied until a suitable dose is found for you.

Children: the initial dose is usually 1.25mg to 2.5mg per square meter of body surface area. These doses may be increased in small steps until a suitable dose is found for you.

Elderly - your doctor will decide whether these medicines are suitable for you. The tablets should be swallowed whole with a glass of water.

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Elderly - your doctor will decide whether these medicines are suitable for you. The tablets should be swallowed whole with a glass of water.
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.

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:
• dizziness, feeling faint or loss of alertness

Common: may affect up to 1 in 10 people:
• low blood pressure, especially in elderly patients
• heart rate, fast breathing and drowsiness or confusion
• trouble passing urine
• jaundice (yellowing of the skin and eyes)
• constipation, which may become severe and stop food moving through the bowel

Rare: may affect up to 1 in 1,000 people:
• breathlessness
• insomnia
• difficulty passing urine
• high blood sugar (hyperglycaemia)
• feeling confused

Older 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.

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 storage temperature 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. If the expiry date expires, please return to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of 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

This medicinal product contains: lactose monohydrate, pregelatinized maize starch, silicon dioxide and 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 ‘L2’ 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 ‘L2’ debossing on another side.

Those tablets are supplied in blister packs of 7, 10, 14, 20, 24, 28, 29, 30, 60, 64, 80, 90, 100 and 112 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Morningside Pharmaceuticals Limited
Unit C, Harcourt Way
Lakeside, Leicestershire, LE9 9TW
United Kingdom

Manufacturer
Morningside Pharmaceuticals Ltd.
5 Purdy Way
Loughborough, LE11 9GW
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