Package leaflet: Information for the user

Levomepromazine hydrochloride 25mg/ml Solution for Injection

Levomepromazine hydrochloride

(Referred to as Levomepromazine Injection in the remainder of the leaflet)

Read all of this leaflet carefully before you are given 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, nurse 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, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Levomepromazine Injection is and what it is used for

Levomepromazine Injection belongs to a group of medicines called phenothiazines. It is used for the relief of severe pain and as a sedative to relieve anxiety and distress associated with severe pain, particularly in terminally ill patients.

This medicine is given by a healthcare professional either by injection into a muscle or vein, or slowly via a needle under the skin.

2. What you need to know before Levomepromazine Injection is given

Do not use Levomepromazine Injection if:
- you are **allergic** (hypersensitivity) to levomepromazine hydrochloride or any of the other ingredients of Levomepromazine Injection (listed in section 6 below). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you are taking any of the following medicines:
  - o citalopram and escitalopram
  - o hydroxyzine
  - o piperaquine
  - o domperidone

Warnings and precautions

Talk to your doctor or nurse before Levomepromazine Injection is given if:
- you have liver or kidney problems
- you are an elderly patient with dementia
- you are elderly, frail, 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 are given the injection. If you receive 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 (antipsychotics) 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 in caution as the risk of a stroke (cerebrovascular accident) may be increased
- you are diabetic or have been told that you have an increased risk of 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 (hyperthyroidism)
- 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. This includes if you are being given Levomepromazine Injection for a long period of time, or 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 (antipsychotics) can, in very rare cases, cause heart rhythm disorders (see section 4).

Other medicines and Levomepromazine Injection

Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription, as they may change the way Levomepromazine Injection works. Do not use Levomepromazine Injection and tell your doctor if you are taking any of the following medicines (see section 2 'Do not use Levomepromazine Injection if'):
- Citalopram and escitalopram – used to treat anxiety and 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 using Levomepromazine Injection, tell your doctor if you are taking any of the following medicines:
- medicines 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, 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 Injection with alcohol

Avoid alcohol while you are having these injections.

Fertility, pregnancy and breast-feeding

Pregnancy

Talk to your doctor or nurse before using this medicine:
- if you are 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 Injection 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.
Breast-feeding 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 whilst receiving

INFORMATION FOR HEALTHCARE PROFESSIONALS

Levomepromazine hydrochloride 25mg/ml Solution for Injection

Please refer to the Summary of Product Characteristics for further information.

Qualitative and quantitative composition

Each ml of the solution contains Levomepromazine hydrochloride 25mg.
For the full list of excipients, see section 6.1.

Pharmaceutical form

Solution for injection.
Clear, colourless solution contained in a clear glass ampoule.

Therapeutic indications

Management of the terminally ill patient.

Levomepromazine resembles chlorpromazine and promethazine in the pattern of its pharmacology. It possesses anti-emetic, antihistamine and anti-adrenaline activity and exhibits a strong sedative effect.

Levomepromazine Injection potentiates the action of other central nervous system depressants but may be given in conjunction with appropriately modified doses of narcotic analgesics in the management of severe pain. Levomepromazine Injection does not significantly depress respiration and is particularly useful where pulmonary reserve is low.

Levomepromazine Injection is indicated in the management of pain and accompanying restlessness or distress in the terminally ill patient.

Posology and method of administration

Intramuscular and intravenous injection

Dosage varies with the condition and individual response of the patient. Levomepromazine Injection may be administered by intramuscular injection or intravenous injection after dilution with an equal volume of normal saline.

The usual dose for adults and the elderly is 12.5mg to 25mg (0.5ml to 1ml) by intramuscular injection, or by the intravenous route after dilution with an equal volume of normal saline immediately before use. In cases of severe agitation, up to 50mg (2ml) may be used, repeated every 6 to 8 hours.

Continuous subcutaneous infusion

Levomepromazine Injection may be administered over a 24 hour period via a syringe driver. The required dose of Levomepromazine Injection (25mg to 200mg per day) should be diluted with the calculated volume of normal saline. Diamorphine hydrochloride is compatible with this solution and may be added if greater analgesia is required.

Levomepromazine tablets 25mg may be substituted for the injection if oral therapy is more convenient.

Children

Clinical experience with parenteral levomepromazine in children is limited.
Where indicated, doses of 0.35mg/kg/day to 3.0mg/kg/day are recommended

Pharmaceutical particulars

Ascorbic acid
Sodium sulfite
Sodium chloride
Water for Injections.

Levomepromazine Injections as it may make you feel drowsy, confused, disorientated, dizzy or lightheaded.

Levomepromazine Injection contains:
- **Sodium:** This medicine contains less than 1mmol sodium (23mg) per millilitre, that is to say essentially 'sodium-free'
- **Sulphites:** May rarely cause hypersensitivity reactions and bronchospasm.

3. How Levomepromazine Injection is given

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or nurse if you are not sure.
Your doctor will prescribe the appropriate dosage for your condition. The medicine will be given to you by a healthcare professional, either by injection into a muscle or vein or slowly via a needle under your skin.

Adults, including the elderly
- The usual dose is half to one vial by injection, although up to two vials may be used. This dose may be repeated every 6 to 8 hours if required.

Alternatively a dose of up to 8 vials diluted with saline may be infused over 24 hours.

Levomepromazine Tablets 25mg may be given instead of Levomepromazine Injection if oral therapy is more convenient.

Use in children
- If the injection is given to children, the dose will be calculated according to their weight; usually 0.35mg – 3.0mg/kg/day.

If you are given more Levomepromazine Injection than you should
As this product will be given to you under medical supervision, it is unlikely that you will be given too much. However, speak to your doctor or nurse if you are worried. Symptoms of overdose include: drowsiness or loss of consciousness, convulsions, low blood pressure, irregular heartbeats and hypothermia (abnormally low body temperature) and severe extrapyramidal dyskinesias (involuntary movements).

If a Levomepromazine Injection is missed
Contact your doctor or nurse as soon as you remember to arrange another appointment for your next injection.
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.

Tell your doctor or nurse immediately if you notice any of the serious side effects – you may need urgent medical treatment:
- you have an **allergic reaction.** 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. This may be an indication that you are sensitive to the medicine and should not be given a repeat dose.

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 prologation 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, pale complexion, stiff muscles, fast heart rate, fast breathing, difficulty passing urine 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.

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 the directly via the Yellow Card Scheme, website: www.mhra.gov.uk/yellowcard or search for the 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 Injection

This medicine will be kept by your doctor or nurse out of the sight and reach of children.
Do not have this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month. If you are not sure when this is, check with your doctor or nurse.
Store below 25°C. Protect from light. You will not be asked to store your medicine. It will be brought to you ready to be given straight away.
Do not throw away any medicines via wastewater or household waste. Your hospital pharmacist will dispose of any medicine no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Levomepromazine Injection contains
The active ingredient is levomepromazine hydrochloride (25mg/ml) per 1 ml ampoule.

The other ingredients are ascorbic acid, sodium sulfite, sodium chloride and water for injections (see end of Section 2 for further, important information on sodium).

What Levomepromazine Injection looks like and contents of the pack
Levomepromazine Injection is a clear, colourless solution for injection. It is supplied in packs of 10 colourless neutral Type **I** glass ampoules per pack.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder in the UK:
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer
CP Pharmaceuticals Ltd,
Ash Road North,
Wrexham, LL13 9UF,
UK.

Steriscience Sp. z o.o.,
10 Daniszewska Street,
Warsaw, 03-230,
Poland

Other formats:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK only).

Please be ready to give the following information:

Product name	Reference number
Levomepromazine Injection	29831/0462

This is a service provided by the Royal National Institute of Blind People.

This leaflet was last revised in 10/2023

WOCKHARDT

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Incompatibilities
Incompatible with alkaline solutions.

Shelf life
3 years

Special precautions for storage
Store below 25°C. Store in the original container and protect from light.

The product should be used immediately after opening. The completion of administration may last up to 24 hours in a closed system if necessary.

Nature and contents of container
1ml neutral glass (Type 1) ampoule. Each pack contains 10 ampoules.
Not all pack sizes may be marketed.

Special precautions for disposal and other handling
Levomepromazine Injection may be administered by intramuscular injection or intravenous injection after dilution with an equal volume of normal saline, or by continuous subcutaneous infusion with an appropriate volume of normal saline. Diamorphine hydrochloride is compatible with this solution.

Marketing Authorisation Holder in UK
Wockhardt UK Ltd, Ash Road North, Wrexham, LL13 9UF, UK

Marketing Authorisation Number
PL 29831/0462

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