**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 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 symptoms 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 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 you take Levomepromazine Injection

**Do not take Levomepromazine Injection:**
- if you are **allergic** to levomepromazine hydrochloride or any of the other ingredients of this medicine (listed in section 6 and end of section 2)

**Warnings and precautions**
Talk to your doctor before taking Levomepromazine Injection
- if you have liver problems
- if you are elderly, frail or have heart disease 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)
- if you suffer from slow or irregular heartbeats/palpitations (Torsades de Pointes) or have a family history of heart problems
- if 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
- if you are diabetic or have been told that you have an increased risk of diabetes
- if you already know you have low levels of potassium, calcium or magnesium in your blood
- if you find it difficult, or are unable, to eat
- if you are an alcoholic
- if you have epilepsy

**Additional tests** will be done by your doctor at the start of treatment, 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. These tests might include an ECG (electrocardiogram) to check your heart is working normally and/or blood tests.

**Other medicines and Levomepromazine Injection**
Tell your doctor 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. These include:

- medicines for the treatment of irregular heartbeats
- antidepressants such as amitriptyline and amitriptylinoxide and drugs for other mental health disorders (i.e. antipsychotics)
- desferrioxamine (for iron poisoning)
- adrenaline (epinephrine) in patients overdosed with antipsychotic drugs.

**Levomepromazine Injection with drink**
Avoid alcohol while you are having these injections.

**Pregnancy and breast-feeding**
If you are pregnant, planning to become pregnant or breast-feeding, ask your doctor or pharmacist before taking any medicine.

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.

**Driving and using machines**
Do not drive or operate machinery whilst receiving Levomepromazine Injections as it may make you feel drowsy, confused, dizzy or lightheaded.

**Important information about some of the ingredients of Levomepromazine Injection**
Sodium – this medicinal product is essentially 'sodium-free' as it contains less than 1mmol sodium (23mg) per millilitre.

## 3. How to take Levomepromazine Injection

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 0.35 mg – 3.0 mg/kg/day

**If you take 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).

**If you forget to take Levomepromazine Injection**
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.

**SEEK medical help immediately if you have any of the following allergic reactions:**

**Allergic reaction –** if following your injection you experience symptoms such as skin rash, swelling or breathing difficulties, **inform your**

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**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.

**doctor immediately.** This may be an indication that you are sensitive to the medicine and should not be given a repeat dose.

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

**If any of these side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor**

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 the national reporting systems listed below.

**United Kingdom**
Yellow Card Scheme
www.mhra.gov.uk/yellowcard

**Malta**
ADR Reporting
www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Levomepromazine Injection

Keep this medicine out of the sight and reach of children.
Store below 25°C. Protect from light. Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

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 protect the environment.

## 6. Contents of the pack and other information

**What Levomepromazine Injection contains**
The active substance 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**
Wockhardt UK Ltd,
Ash Road North,
Wrexham,
LL13 9UF,
UK.

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

**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 02/2017**

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*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.

**Incompatibilities**
Incompatible with alkaline solutions.

**Shelf life**
3 years

**Special precautions for storage**

Store below 25ºC. 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**
Wockhardt UK Ltd
Ash Road North
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**Marketing Authorisation Number**

PL 29831/0462
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