

Package leaflet: Information for the patient

**Clopixol[®] 200 mg/ml solution for injection
zuclopenthixol decanoate**

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

What is in this leaflet:

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

The name of your medicine is Clopixol 200 mg/ml solution for injection (called Clopixol Injection in this leaflet). Clopixol Injection contains the active substance zuclopenthixol. It belongs to a group of medicines known as antipsychotics (also called neuroleptics).

These medicines act on nerve pathways in specific areas of the brain and help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

Clopixol Injection is used for the treatment of schizophrenia and other psychoses.

Your doctor, however, may prescribe Clopixol Injection for another purpose. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

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

Clopixol Injection is not given

- If you are allergic (hypersensitive) to zuclopenthixol, other thioxanthene drugs or antipsychotic drugs or any of the other ingredients of this medicine (listed in section 6). Tell your doctor if you think you might be
- If you are feeling less alert than usual, or are drowsy or sleepy or have serious problems with your blood circulation

Warnings and precautions

Talk to your doctor, pharmacist or nurse before Clopixol Injection is given to you:

- If you have a heart condition, including an irregular heart beat (such as a slower heart beat); have had a recent heart attack or have problems that cause ankle swelling or shortness of breath
- If you have severe breathing problems (such as asthma or bronchitis)
- If you have liver, kidney or thyroid problems
- If you suffer from epilepsy, or have been told that you are at risk of having fits (for example because of a brain injury or because of alcohol withdrawal)
- If you suffer from Parkinson's disease, or myasthenia gravis (a condition causing severe muscular weakness)
- If you have an enlarged prostate or suffer from a condition known as pheochromocytoma (a rare type of cancer of a gland near the kidney)
- If you suffer from glaucoma (raised pressure within the eye)
- If you have risk factors for stroke (e.g. smoking, hypertension)
- If you have too little potassium or magnesium in your blood or a family history of irregular heart beats
- If you use other antipsychotic medicines
- If you suffer from diabetes
- If you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- If you are being treated for cancer.

Children and adolescents

Clopixol Injection is not recommended in these patients.

Other medicines and Clopixol Injection

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines should not be taken at the same time as Clopixol Injection:

- Medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Tricyclic antidepressants
- Barbiturates or other medicines that make you feel drowsy
- Anticoagulant drugs used to prevent blood clots (e.g. warfarin)
- Anticholinergic drugs (contained in some cold, allergy or travel sickness remedies as well as other medicines)
- Metoclopramide (used to treat nausea and other stomach conditions)
- Piperazine (used to treat worm infections)
- Levodopa or other medicines used to treat Parkinson's disease
- Sibutramine (used to reduce appetite)
- Digoxin (to control heart rhythm)
- Corticosteroids (e.g. prednisolone)
- Medicines used to lower the blood pressure such as hydralazine, alpha blockers (e.g. doxazosin) beta-blockers, methyl dopa, clonidine or guanethidine

- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of zuclopenthixol in your blood
- Medicines used to treat epilepsy.
- Medicines used to treat diabetes

Clopixol Injection can reduce the effect of adrenaline (epinephrine) and similar drugs.

Tell your doctor, dentist, surgeon or anaesthetist before any operation as Clopixol Injection can increase the effects of general anaesthetics, muscle relaxing drugs and drugs used to prevent clots.

Clopixol Injection with alcohol

Clopixol Injection may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment with Clopixol Injection.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Your newborn baby might show side effects if this medicine is used during pregnancy.

The following symptoms may occur in newborn babies, of mothers that have used Clopixol 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

If you are breastfeeding, ask your doctor for advice. Clopixol Injection should not be used when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility

Zuclopenthixol may decrease your sexual activity and fertility. These are not lasting effects. Please talk to your doctor about any problems.

Driving and using machines

There is a risk of feeling drowsy and dizzy when being treated with Clopixol Injection, especially at the start of your treatment. If this happens do not drive or use any tools or machines until you know you are not affected in this way.

Do not drive if you have blurred vision.

3. How Clopixol Injection is given

A small amount of Clopixol Injection is drawn up into a syringe and then injected into muscle of your buttock or thigh.

Your doctor will decide on the correct amount of medicine to give, and how often to give it. The medicine is slowly released from the injection site so that a fairly constant amount of medicine gets into your blood during the period between each dose.

Adults

The usual dose lies between 200-500 mg every 1 to 4 weeks but some patients require 600 mg every week. The maximum single dose at any one time is 600 mg. If you need more than 2 ml of medicine it will probably be divided between 2 injection sites.

If you haven't received an injection like Clopixol Injection before, a small dose of 100 mg is usually given one week before your normal dose to test how well you tolerate the medicine.

If you have been treated with Clopixol tablets and you are being transferred to Clopixol Injection you may be asked to continue taking the tablets for several days after the first injection.

Your doctor may decide to adjust the amount given, or the interval between injections, from time to time.

If you have liver problems, the level of zuclopenthixol in your blood may be checked.

Older patients (above 65 years of age)

Starting doses for older or frail patients are usually reduced to a quarter or a half of the dosage range.

Patients with special risks

If you have renal failure, your dosage should be reduced to half the usual dosage range. If you have liver problems, the level of zuclopenthixol in your blood may be checked. Patients with liver complaints normally receive doses at half the usual dosage range.

Use in children

Clopixol Injection is not recommended for children.

Duration of treatment

It may take between four and six months before you feel better. Your doctor will decide the duration of treatment.

It is important that you continue to receive your medicine at regular intervals even if you are feeling completely well, because the underlying illness may persist for a long time. If you stop your treatment too soon your symptoms may return.

If you feel that the effect of Clopixol Injection is too strong or weak, talk to your doctor or pharmacist.

If you are given too much Clopixol Injection

Your medicine will be given by your doctor/nurse.

In the unlikely event that you receive too much Clopixol Injection you may experience some symptoms.

Symptoms of overdose may include:

- Drowsiness
- Unconsciousness
- Muscle movements or stiffness
- Fits
- Low blood pressure, weak pulse, fast heart rate, pale skin, restlessness
- High or low body temperature
- Changes in the heartbeat including irregular heartbeat or slow heart rate

You will receive treatment for any of these symptoms from your doctor or nurse.

4. Possible side effects

Like all medicines, Clopixol Injection can cause side effects, although not everybody gets them. Older people tend to be more likely to suffer from some of these effects than younger people and this may mean your treatment is supervised more closely.

Serious side effects

Stop using Clopixol and seek medical advice immediately if you have any of the following allergic reactions:

- Difficulty in breathing
- Swelling of face, lips, tongue or throat which causes difficulty in swallowing or breathing
- Severe itching of the skin (with raised lumps)

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.

If you get any of the following symptoms you should **contact your doctor immediately** as your dose may need to be reduced or stopped:

- High fever, unusual stiffness of the muscles and changes in consciousness, especially if occurring with sweating and fast heart rate. These symptoms may be signs of a rare but serious condition called neuroleptic malignant syndrome that has been reported with the use of Clopixol and similar medicines
- Unusual movements of the mouth and tongue as these may be early signs of a condition known as tardive dyskinesia
- Unusual muscle movements (such as circular movements of the eyes), stiffness, tremor and restlessness (for example difficulty in sitting or standing still) as these may be signs of a so-called “extra-pyramidal” reaction
- Any yellowing of the skin and the white of the eyes (jaundice); your liver may be affected

Other side effects

Side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment.

- Throbbing or fast heartbeats

- Reduction in blood platelets (which increases the risk of bleeding or bruising) and other blood cell changes.
- Drowsiness
- Loss of co-ordination or altered muscle movements (including unusual movements of the mouth, tongue and eyeballs)
- Tremor
- Stiff or floppy muscles (including stiff jaw and neck muscles)
- Dizziness or vertigo
- Headache or migraine
- Numbness or tingling in the arms and legs
- Poor concentration, loss of memory or confusion
- A changed walking pattern
- Abnormal reflexes
- Rigidity of the whole body
- Fainting
- Speech problems
- Fits
- Enlarged pupils or blurred, abnormal vision
- Sensitive hearing or ringing in the ears (tinnitus)
- Stuffy nose
- Shortness of breath
- Dry mouth or increase in saliva
- Feeling sick or vomiting
- Indigestion or stomach pain
- Flatulence (wind), constipation or diarrhoea
- Abnormal urination (increases or decreases in the frequency or amount)
- Increased sweating or greasy skin
- Itching, rashes or skin reactions (including sensitivity to sunlight)
- Skin reactions at injection site
- Changes in skin colour
- Bruising under the skin
- Muscle pain
- Raised blood levels of glucose, lipids or the hormone prolactin
- Loss of control of blood sugar levels
- Changes in appetite or weight
- Low blood pressure
- Hot flushes
- General weakness or pain, tiredness or feeling unwell
- Increased thirst
- Reduced or increased body temperature (including fever)
- Abnormal liver function tests
- Liver enlargement
- Unexpected excretion of breast milk
- Insomnia, abnormal dreams or nightmares
- Depression or anxiety
- Nervousness or agitation
- Lack of emotion or indifference to your surroundings (apathy)

- Changes to your sex drive
- Men may experience breast enlargement or problems with ejaculation or erections (including prolonged erections)
- Women may experience an absence of menstrual periods, vaginal dryness or problems with orgasms

As with other medicines that work in a way similar to zuclopenthixol (the active ingredient of Clopixol), rare cases of the following side effects have been reported:

- Slow heartbeat and abnormal ECG heart tracing
- Life threatening irregular heart beats

In rare cases irregular heart beats (arrhythmias) may have resulted in sudden death.

In 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.

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 (see details below)

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

United Kingdom

Via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Alternatively you can call Freephone 0800 100 3352 (available between 10am-2pm Monday – Friday) or fill in a paper form available from your local pharmacy.

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

Sir temi Zammit Buildings

Malta Life Sciences Park

San Gwann SGN 300

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Clopixol Injection

Usually your doctor or nurse will store the medicine for you. If you keep it at home:

- Keep this medicine out of the sight and reach of children
- Do not use this medicine after the expiry date that is printed on the label and carton after EXP. The expiry date refers to the last day of that month
- Keep the ampoules in the outer carton in order to protect from light.

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 to protect the environment.

6. Contents of the pack and other information

What Clopixol Injection contains

The active substance is zuclopenthixol decanoate.

Each millilitre (ml) of Clopixol Injection contains 200 mg zuclopenthixol decanoate.

The other ingredient is thin vegetable oil.

What Clopixol Injection looks like and contents of the pack

Clopixol Injection is an oily liquid.

Clopixol Injection is available in glass ampoules containing 1 ml (200 mg) in cartons of 10 ampoules and single-packed vials of 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

For any information about this medicine, please contact the Marketing Authorisation holder:

Lundbeck Limited
2nd floor
Building 3, Abbey View
Everard Close
St Albans
AL1 2PS
UK

Manufacturer

H. Lundbeck A/S
Ottiliavej 9
DK-2500 Valby
Denmark

This leaflet was last revised in 12/2016

To request a copy of this leaflet in braille, large print or audio please call free of charge:

0800 198 5000

Please be ready to give the following information:

| Product name | Product code number |
|---------------------|----------------------------|
| Clopixol Injection | PL 0458/0017 |

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



The following information is intended for healthcare professionals only:

Clopixol 200 mg/ml solution for injection

Administration information for the healthcare professional

Consult the Summary of Product Characteristics for full information on this product

Clopixol 200 mg/ml solution for injection is a clear, yellowish oil, practically free from particles. It should be administered by deep intramuscular injection into the upper outer buttock or lateral thigh.

The maximum single dose at any one time is 600 mg. For example, 1200 mg every 2 weeks should not be given.

Note: As with all oil based injections it is important to ensure, by aspiration before injection, that inadvertent intravascular entry does not occur.

Injection volumes of greater than 2 ml should be distributed between two injection sites. This product may be mixed in the same syringe with other products in the Clopixol Injection range, including Clopixol-Acuphase Injection (zuclopenthixol acetate 50 mg/ml).

It should not be mixed with any other injection fluids.