

This medicine is marketed by a doctor's prescription only

CLOPIXOL DEPOT
200 mg/mL

CLOPIXOL DEPOT
500 mg/mL

Prolonged release solution for injection

Composition: 1 mL of prolonged release solution for I.M injection contains 200 mg or 500 mg of Zuclopenthixol decanoate.

Inactive ingredients: See section 6

- **Read the entire leaflet carefully before using this medicine.** This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or the pharmacist.
- This medicine was prescribed to treat your illness. Do not pass it to others. It may harm them even if it seems to you that their illness is similar to your own.

1. What is the medicine being used for?

CLOPIXOL DEPOT is taken to treat acute schizophrenia and other psychoses especially when oral administration of drugs is not possible.

Therapeutic group: Neuroleptic (antipsychotic) drugs

CLOPIXOL DEPOT is a drug that belongs to the antipsychotic drug group (which is also called the neuroleptic group). These medicines affect certain neural pathways in the brain and helps correct the chemical imbalance in the brain that causes your symptoms.

2. Before using this medicine

Do not use the medicine 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.
- You are feeling less alert than usual, or are drowsy or sleepy or have serious problems with your blood circulation.

Special warnings regarding the use of the medicine

Before using Clopixol Depot, tell your doctor :

- 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 phaeochromocytoma (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 medications like these have been associated with the formation of blood clots
- If you are being treated for cancer

Children and adolescents

Clopixol Depot is not recommended for use in children due to lack of clinical experience.

Drug interactions:

If you are taking or have recently taken other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

This is especially important if you are taking medicines for:

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

- 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, methyldopa, 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 Depot can reduce the effect of adrenaline (epinephrine) and similar drugs.

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

Taking this medicine and alcohol consumption

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

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

If you are pregnant or think you might be pregnant, tell your doctor. Clopixol Depot should not be used during pregnancy unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Clopixol Depot 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 breast-feeding, ask your doctor for advice.

Clopixol Depot 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 Depot, 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 to take this medicine?

Always use according to the doctor's instructions.
Check with your doctor or pharmacist if you are not sure.

This medicine is an intramuscular injection (injected into the muscle of the buttox). It should be given by a doctor or a nurse.

The medicine is slowly released from the injection site, so that a constant amount of medicine gets into your blood between injections.

The intervals between injections and the dosage will be determined according to the doctor's instructions only.

Adults

Clopixol Depot 200 mg/mL:

The usual dose is between 1 - 2 mL every 2 - 4 weeks.

Some patients may need higher doses or shorter intervals between doses.

Injection volumes exceeding 2 ml will probably be divided between two injection sites.

If volumes larger than 2-3 ml of the 200 mg/ml solution are required, the more concentrated solution (Clopixol Depot 500 mg/ml) should be preferred.

Clopixol Depot 500 mg/mL:

The usual dose is between 0.5-1 mL every 1-4 weeks.

If you are switching from Clopixol tablets to Clopixol Depot injections, you may be asked to continue taking the tablets for several days after the first injection.

Your doctor might change your dose or intervals from time to time.

Elderly patients (above 65 years)

Usually a lower dose would be given.

Use in children

Clopixol Depot is not recommended for children.

Patients with special risks:

Reduced liver function patients: usually a lower dose would be given.

If you feel that this medicine is too strong or too weak for you, talk to your doctor or pharmacist.

Do not exceed the recommended dose.

Do not swallow.

Treatment duration:

It is important that you will get your treatment at the intervals your doctor ordered. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your doctor, as your symptoms might return. The duration of your treatment will be determined by your doctor.

If you were given too much Clopixol Depot

This medicine is injected to you by a doctor or a nurse. In the unlikely event that you were given too much of it- you might feel the following over-dosage symptoms:

Drowsiness, unconsciousness, fits, unusual movements, seizures, shock, low blood pressure, weak pulse, heart palpitations, paleness, restlessness, elevated or reduced body temperature; changes in the heart beat, including irregular heart beat or slow heart rate were reported when Clopixol Depot was given in overdose levels together with other medicines that affect the heart rate.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any further questions on the use of the medicine, consult the doctor or pharmacist.

4. Side effects:

As with all medicines, use of Clopixol Depot may cause side effects in some users. 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.

Do not be alarmed when reading the list of side effects. You may not experience any of them.

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 the 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.

Very common side effects (affects more than 1 in 10 people):

Somnolence, akathisia, hyperkinesia, hypokinesia, dry mouth.

Common side effects (may affect up to 1 in 10 people):

Increased appetite, weight increased, insomnia, depression, anxiety, nervousness, abnormal dreams, agitation, libido decreased, tremor, dystonia, hypertonia, dizziness, headache, paraesthesia, disturbance in attention, amnesia, gait abnormal, accommodation disorder, vision abnormal, vertigo, tachycardia, palpitations, nasal congestion, dyspnoea, salivary hypersecretion, constipation, vomiting, dyspepsia, diarrhoea, hyperhidrosis, pruritus, myalgia, micturition disorder, urinary retention, polyuria, asthenia, fatigue, malaise, pain.

Uncommon side effects (may affect up to 1 in 100 people):

Decreased appetite, weight decreased, apathy, nightmare, libido increased, confusional state, tardive dyskinesia, hyperreflexia, dyskinesia, parkinsonism, syncope, ataxia, speech disorder, hypotonia, convulsion, migraine, oculogyration, mydriasis, hyperacusis, tinnitus, hypotension, hot flush, abdominal pain, nausea, flatulence, liver function test abnormal, rash, photosensitivity reaction, pigmentation disorder, seborrhoea, dermatitis, purpura, muscle rigidity, trismus, torticollis, ejaculation failure, erectile dysfunction, female orgasmic disorder, vulvovaginal dryness, thirst, hypothermia, pyrexia.

Rare side effects (may affect up to 1 in 1000 people):

Thrombocytopenia, neutropenia, leukopenia, agranulocytosis, hypersensitivity, anaphylactic reaction, hyperprolactinaemia, hyperglycaemia, glucose tolerance impaired, hyperlipidaemia, electrocardiogram QT prolonged, gynaecomastia, galactorrhoea, amenorrhoea, priapism.

As with other drugs belonging to the therapeutic class of antipsychotics, rare cases of QT prolongation, ventricular arrhythmias - ventricular fibrillation, ventricular tachycardia, Torsade de Pointes and sudden unexplained death have been reported for zuclopenthixol.

Very rare side effects (may affect up to 1 in 10000 people):

Neuroleptic malignant syndrome, venous thromboembolism, cholestatic hepatitis, jaundice.

side effects with unknown frequency (frequency can not be estimated from the available data):

Drug withdrawal syndrome neonatal.

Cases of venous thromboembolism, including cases of pulmonary embolism and cases of deep vein thrombosis have been reported with antipsychotic drugs – frequency unknown.

Abrupt discontinuation of zuclopenthixol may be accompanied by withdrawal symptoms. The most common symptoms are nausea, vomiting, anorexia, diarrhoea, rhinorrhoea, sweating, myalgias, paraesthesias, insomnia, restlessness, anxiety, and agitation. Patients may also experience vertigo, alternate feelings of warmth and coldness, and tremor. Symptoms generally begin within 1 to 4 days of withdrawal and abate within 7 to 14 days.

If you get any side effects, if any of the side effects gets worse, or if you suffer from any side effect not listed in the leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il), which leads to an online form for reporting side effects.

Alternatively you can use the following link:

<https://sideeffects.health.gov.il/>

5. How to store the medicine?

Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and /or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use this medicine after the expiry date stated on the package. The expiry date refers to the last day of that month.

Storage condition:

- Store in a temperature below 25°C
- 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 protect the environment.

6. Additional information:

In addition to the active ingredient the medicine also contains: Medium chain triglycerides.

What the medicine looks like and contents of the pack:

Clopixol Depot 200 mg/mL, solution for injection, is available as ampoules, packed in a carton. Packaging sizes:

- a package containing one ampoule of 1 ml
- a package containing ten ampoules of 1 ml

Clopixol Depot 500 mg/mL, solution for injection, is available as ampoules (1 mL), packed in a carton:

- a package containing one ampoule of 1 ml
- a package containing five ampoules of 1 ml

Clopixol Depot is a clear yellowish oily fluid, practically free from particles.

Name and address of the license owner:

Lundbeck Israel Ltd., 11 Galgaley Haplada, P.O.B. 13105, Herzliya 4672211

Fax : 03- 9100116 **E-Mail :** Israel@lundbeck.com

Name and address of the manufacturer: H.Lundbeck A/S, Ottiliavej 9, DK-2500 Valby, Denmark

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**Registration number of the medicine in the National Drug Registry Of the
Ministry of Health:**

Clopixol Depot 200 mg/ mL 069 70 25491

Clopixol Depot 500 mg/ mL 047 81 25969
