

**PATIENT PACKAGE INSERT IN  
ACCORDANCE WITH THE PHARMACISTS'  
REGULATIONS (PREPARATIONS) – 1986**

This medicine is marketed only with prescription

<b>CLOPIXOL</b>	<b>CLOPIXOL</b>	<b>CLOPIXOL</b>	<b>CLOPIXOL</b>
	<b>2 mg</b>	<b>10 mg</b>	<b>25 mg</b>
Drops	Tablets	Tablets	Tablets

<b>Composition</b> (active ingredient):	<b>Composition</b> (active ingredient):	<b>Composition</b> (active ingredient):	<b>Composition</b> (active ingredient):
Zuclopenthixol (as dihydrochloride ) 20 mg/ml (1 drop = 1 mg)	Zuclopenthixol (as dihydrochloride ) 2 mg	Zuclopenthixol (as dihydrochloride ) 10 mg	Zuclopenthixol (as dihydrochloride ) 25 mg

Inactive ingredients: See section 6

- **Read this package insert carefully in its entirety before using this medicine.** This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or 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.
- This medicine is not intended to be used by children.

**1. What is the medicine being used for?**

CLOPIXOL can be taken to treat acute schizophrenia and other acute psychoses.

**Therapeutic group:** anti-psychotic drugs, Thioxanthene derivative.

CLOPIXOL contains the active substance zuclopenthixol. It 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 certain cases of chemical imbalance in the brain that cause your symptoms.

**2. Before using this medicine**

**Do not take this medicine if**

- You are sensitive (allergic) to the active ingredient (zuclopenthixol) or any of the other ingredients of Clopixol (listed in section 6).
- If you are affected by alcohol, strong pain medication (morphine), or anti-epileptic drugs (phenobarbital).
- If you have a severe drop in blood pressure or heart failure.
- Please note: Unconscious patients should not be given Clopixol.

### **Warnings and precautions**

#### **Before using Clopixol, tell your doctor if:**

- You have a liver disease.
- You suffer from or have a history of cramps or seizures.
- You have diabetes (It may be necessary to adjust your dose of insulin and/or other antidiabetic medications).
- You have brain damage due to alcohol poisoning or the use of organic solvents.
- You consume large amounts of alcohol or strong pain medication (morphine and morphine-like medication).
- You have, or have a history of, heart disease.
- Someone in your family has heart disease or a slow heart rate and changes on the ECG [electrocardiogram] graph (QT extension).
- You are taking other medication for your mental disorder (e.g. lithium, haloperidol, perphenazine).
- You are developmentally disabled.
- You or someone else in your family have a history of blood clots as medications such as this one have been associated with the formation of blood clots.

#### **Further warnings:**

- Some patients (e.g. the elderly and senile) have a greater risk of strokes. Talk to your doctor.
- Contact your doctor immediately if you develop a high fever with stiffness of the muscles and movements, profuse sweating, and reduced consciousness (malignant neuroleptic syndrome). This may be life-threatening and requires immediate medical attention.
- Clopixol drops are harmful for alcoholics.  
As Clopixol drops contains ethanol, pregnant women and breast-feeding women as well as patients with epilepsy or liver disease should only take Clopixol drops as discussed with a doctor.
- Always inform the staff that you are being treated with Clopixol when having blood and urine tests taken.  
This medicine may affect the test results.

### **Other medicines and Clopixol**

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplements, inform your doctor or pharmacist.**

This is especially important if you are taking medicines for:

- Abnormal heart rhythm (e.g. amiodarone, sotalol)
- Mental disorders (e.g. lithium, haloperidol, perphenazine)
- Tricyclic antidepressants (e.g. amitriptyline, imipramine)
- Anxiety, agitation, sleeplessness (e.g. diazepam, flunitrazepam)
- Epilepsy (barbiturates, e.g. phenobarbital)
- Parkinson's disease (e.g. biperiden, levodopa)
- High blood pressure (e.g. guanethidine)
- Infections (e.g. erythromycin, moxifloxacin)
- Gastrointestinal diseases (e.g. metoclopramide)
- Adrenergic agents, such as asthma medications (e.g. salbutamol, terbutaline)
- Allergies (certain antihistamines)- talk to your doctor
- Also, if you take diuretics (such as bendroflumethiazide, furosemide).

Clopixol drops contain ethanol. Do not take Clopixol drops if you are being treated with disulfiram (drug used in alcohol dependence) or metronidazole (to treat an infection). Talk to your doctor.

Some medicines may interact with Clopixol and Clopixol may affect the way other medicines work. This is normally of no practical significance. Ask your doctor or pharmacist for more information.

#### **This medicine and food**

Clopixol may be taken with or without food.

**Clopixol drops:** may be taken with water, orange juice or apple juice.

#### **This medicine and alcohol consumption**

Clopixol may increase the effect of alcohol and make you drowsier. Therefore, do not drink alcohol while you are being treated with Clopixol.

#### **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 you should only take this medicine as directed by your doctor.

Clopixol drops contain alcohol. Only take Clopixol drops as discussed with your doctor.

The following symptoms may occur in newborn babies if the mothers were treated with Clopixol during the last trimester (the last three months of the pregnancy):

Tremors, muscle stiffness and/or weakness, sleepiness, agitation, difficulties breathing and eating.

If your baby develops any of these symptoms, contact your doctor.

#### **Breast-feeding**

If you are breast-feeding, consult your doctor before using this medicine.

#### **Fertility**

Studies in animals showed that Clopixol affects fertility. Ask your doctor for advice.

### **Driving and using machines**

Clopixol can cause drowsiness to a greater or lesser degree. Please take this into consideration when driving and operating machines.

### **Important information about some of the ingredients in Clopixol**

**Clopixol drops** contains 120 mg of alcohol (ethanol 96%) in each ml which is equivalent to 14.2% v/v. The amount in 1 ml of this medicine is equivalent to less than 3 ml of beer or 2 ml of wine.

The small amount of alcohol in this medicine will not have any noticeable effects. Clopixol drops is harmful to alcoholics.

You should only use this medicine as discussed with your doctor if you consume large amounts of alcohol, have epilepsy or liver disease, or if you are pregnant or breast-feeding.

Do not take **Clopixol drops** if you are being treated with disulfiram (drug used in alcohol dependence) or metronidazole (to treat an infection). Talk to your doctor.

**Clopixol tablets** contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor, before taking Clopixol tablets.

Clopixol tablets also contains hydrogenated castor oil, which may cause stomach upset and diarrhea.

### **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.

Dosage is according to doctor's instructions only. The dose may vary significantly and depends on the severity of the illness.

Usual recommended dose is:

Adults

Schizophrenia, mania and other psychoses:

Initial dose varies between 10-50 mg daily (in Clopixol drops: 10-50 drops daily).

Your dose may be gradually increased up to 75 mg daily (in Clopixol drops: 75 drops daily).

In some patients a much higher dose is needed. Maximum dosage per single dose is 40 mg and the maximum daily dose is 150 mg (in Clopixol drops: 150 drops daily).

The maintenance dose is usually 20-40 mg per day (in Clopixol drops: 20-40 drops daily).

Patients in special risk groups:

Elderly and hepatic impairment patients, usually receive the lower end of the dosage range.

Use in children:

Clopixol should not be given to children .

**Do not exceed the recommended dose**

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

**Directions for use:**

Tablets: Do not chew! Swallow the medicine with a small amount of water.

Drops: add the required amount of medicine drops into a drink (water, orange or apple juice), mix lightly and drink the whole amount.

In the beginning of the treatment Clopixol should usually be taken in 2 or 3 separate doses during the day.

In the maintenance treatment Clopixol can be taken as a single daily dose.

**Treatment duration:**

Like with other anti-psychotic treatments, you may feel better only after about two weeks of treatment. The duration of your treatment will be determined by your doctor. It is important that you will get your treatment for as long as your doctor ordered. Even if there is an improvement in your health, do not stop treatment with this medicine without consulting your doctor or pharmacist, as your symptoms might return.

Do not change the dosage without consulting your doctor.

**Administration:**

Turn the bottle completely upside down. If no drops come out, tap the bottle lightly to start the flow.

**If you have taken too much Clopixol**

If you have taken an overdose, or if a child has accidentally swallowed the medicine, contact immediately the doctor or proceed immediately to a hospital emergency room and bring the package of the medicine with you. Do it even if you don't feel bad or have overdose symptoms.

Symptoms of an overdose may include:

- Drowsiness
- Unconsciousness developing into a coma
- Spasms, involuntary movements
- Muscle movements or stiffness
- Fits
- Low blood pressure, weak pulse, heart palpitations, paleness, restlessness
- Elevated or reduced body temperature

- Changes in the heart rhythm including irregular heart rhythm or slow heart rhythm (may happen when Clopixol has been taken in overdose together with drugs known to affect the heart rate).

#### **If you forget to take Clopixol**

If you forget to take a dose, do not take a double dose to make up for a forgotten one. Take the next dose at the usual time, and consult a doctor.

#### **If you stop taking Clopixol**

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor.

Your doctor will decide when and how to stop the treatment, this is because abrupt discontinuation may cause undesirable effects ( e.g. nausea, vomiting, diarrhea, distaste for food, runny nose, sweating, muscle pain, tingling/prickly sensation of the skin, insomnia, restlessness, anxiety, agitation, tremors, dizziness and a feeling of being too hot or too cold).

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

Talk to your doctor or pharmacist if you have any questions regarding using this medicine.

#### **4.Side effects:**

Like all medicines, Clopixol can cause side effects, although not everybody gets them.

Don't be alarmed by the list of side effects. You may not experience any of them.

**Contact your doctor or go to a hospital immediately** if you experience one of the following symptoms:

#### **Serious side effects**

*Common side effects (may occur in between 1 and 10 in 100 patients)*

-Rapid heart rate. Contact the doctor or the emergency room.

*Uncommon side effects (may occur in between 1 and 10 in 1,000 patients):*

-Convulsions. Contact your doctor or the emergency room immediately.

*Rare side effects (may occur in between 1 and 10 in 10,000 patients):*

- Serious effect on the heart with rapid, possibly irregular heart rate, which can lead to cardiac arrest .

Contact your doctor or the emergency room immediately.

-Sudden hypersensitivity reactions, e.g. skin rash, breathing difficulties and fainting (anaphylactic reaction). Seek immediate medical attention.  
This could be life-threatening.

-Bleeding from the skin and mucous membranes and bruising due to changes in the blood (low platelet count). Seek immediate medical attention.

-General weakness, tendency for inflammation (infections), especially tonsillitis and fever due to changes in the blood (severe lack of white blood cells). Seek immediate medical attention.

*Very rare side effects (may occur in less than 1 in 10,000 patients):*

-High fever, unusual muscle stiffness and effect on consciousness, increased sweating, and palpitations. Seek immediate medical attention. This could be life-threatening.

- Hepatitis, yellowing of the skin and the white part of the eyes (jaundice). Contact the doctor or the emergency room.

### **Non-serious side effects**

*Very common side effects (may occur in more than 1 in 10 patients):*

-Involuntary, slow or rapid movements or muscle stiffness or difficulty sitting or standing still.

- Drowsiness.

-Dry mouth, which can increase the risk of dental cavities.

*Common side effects (may occur in between 1 and 10 in 100 patients)*

- Depression. In some patients, this may develop into a serious side effect. Talk to your doctor.
- Difficulty urinating, possible cessation of urination. In some patients, this may develop into a serious side effect. Talk to your doctor.
- Palpitations.
- Tremors, increased muscle tension, dizziness.
- Headache, reduced ability to concentrate, memory loss.
- Tingling/prickly sensation or numbness of the skin.
- Abnormal gait.
- Blurred vision, visual disturbances.
- Nasal congestion, shortness of breath.
- Increased production of saliva, constipation, vomiting, stomach discomfort, diarrhoea.
- Difficulty urinating, e.g. urge to urinate frequently, involuntary urination.
- Excessive sweating, itching.
- Pain, muscle pain.
- Increased appetite, weight gain.
- Weakness, fatigue, bodily discomfort.
- Insomnia, anxiety, nervousness, abnormal dreams, restlessness, reduced sexual desire.

*Uncommon side effects (may occur in between 1 and 10 in 1,000 patients):*

- Slow, involuntary movements, muscle stiffness.
- Tremors of hands and head, stiff movements and stiff facial expression, rocking and twisting movements, especially of the legs, reduced muscle strength.
- Fainting, uncertain movements, speech disturbances, migraine.
- Circling movements of the eyes, enlarged pupils.
- Increased sensitivity to sound, buzzing in the ears (tinnitus).
- Abdominal pain, nausea, increased flatulence.

- Rash, increased sensitivity of the skin to light, changes in pigmentation, very oily skin.
- Eczema or irritation of the skin, slight bleeding in the skin and mucous membranes.
- Tight clenching of the jaw due to tension in the muscles of mastication, strained tilting of the head.
- Reduced appetite, weight loss, excessive thirst.
- Hot flashes, low body temperature, fever.
- Impotence and lack of ejaculation.
- Lack of orgasm in women, vaginal dryness.
- Indifference, nightmares, increased sexual desire, confusion.

*Rare side effects (may occur in between 1 and 10 in 10,000 patients):*

- Rapid, slow and/or irregular heart rate. This may be serious. Contact your doctor.
- General weakness, tendency for inflammation (infections), especially tonsillitis and fever due to changes in the blood (low platelet count). This may become serious. If you develop a fever you should call your doctor immediately.
- Frequent urination, thirst, fatigue due to high blood sugar (blood glucose). In some patients, this may develop into a serious side effect. Talk to your doctor.
- Increased risk of atherosclerosis due to increased cholesterol in the blood.
- Hypersensitivity.
- Development of breasts in men, persistent and painful erection of the penis.
- Lactic discharge, cessation of menstruation.

Clopidogrel may cause additional side effects, that you would not normally notice. These include changes in certain laboratory tests due to an impact on the blood, the ECG graph and the liver. Test results will return to normal when treatment is discontinued.

Blood clots have been reported in the veins, especially in the legs (symptoms include swelling, pain and redness of the leg). The blood clot may become dislodged and carried by the blood to the lungs causing chest pain and difficulty in breathing. Contact your doctor immediately if you develop any of these symptoms.

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.

**If you have any side effects, if any of the side effects are worsening, or if you notice any side effects not listed in this leaflet, please tell your 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](http://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 safe place out of the sight and reach of children and/ or infants, 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 packaging. The expiry date refers to the last day of that month.

**Storage conditions:**

Drops: Store in a refrigerator (2°-8°C) . Store in original package to protect from light. Upon opening the first time, the drops may be used within 6 weeks when stored below 25 °C.

Tablets 10 mg, 25 mg : Store below 25 °C.

Tablets: 2 mg : Store below 25 °C in original container 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.Further information:**

- In addition to the active ingredient this medicine also contains:

**Tablets:**

Potato Starch, Lactose monohydrate, Cellulose microcrystalline, Talc, Copovidone, Glycerol 85%, Hypromellose (5mPa.s), Castor oil hydrogenated, Magnesium stearate, Red iron Oxide (E172), Macrogol 6000 NF, Titanium dioxide (E171)

Each clopixol 2 mg tablet contains 17.4 mg lactose monohydrate

Each clopixol 10 mg tablet contains 21.6 mg lactose monohydrate

Each clopixol 25 mg tablet contains 22 mg lactose monohydrate

**Drops:**

Purified water, ethanol (96%). Clopixol drops contain 14.2% vol. alcohol (120 mg per mL).

- **What the medicine looks like and contents of the pack:**

Clopixol 2 mg film-coated tablets are round, convex on both sides and pale red.

Clopixol 10 mg film-coated tablets are round, convex on both sides and light reddish brown.

Clopixol 25 mg film-coated tablets are round, convex on both sides and reddish brown.

Clopixol drops are a clear odour- and colourless to yellowish solution with a slightly bitter taste.

Clopixol tablets are available in packages of 50 and 100 tablets in HDPE containers. 20 ml Clopixol drops solution is available in a glass dropper bottle.

**Name and address of the license owner:**

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

**Name and address of the manufacturer:**

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

**Revised in June 2021 according to MoH guidelines.**

Registration number of the medicine in the ministry of health registry:

**2 mg tablets:** 047-84-25485

**10 mg tablets:** 047-86-25486

**25 mg tablets:** 047-85-25487

**drops :** 047-87-25488

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