



## Clopixol®

2 mg film-coated tablets

10 mg film-coated tablets

25 mg film-coated tablets

zuclopenthixol

### Read all of this leaflet carefully before you start taking this medicine

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

### In this leaflet:

1. What Clopixol is and what it is used for
2. Before you take Clopixol
3. How to take Clopixol
4. Possible side effects
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## 1. WHAT CLOPIXOL IS AND WHAT IT IS USED FOR

### How does Clopixol work

Clopixol 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.

### What is Clopixol used for

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

It is also used for the treatment of mania and to control agitation and aggressiveness in mentally handicapped.

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

## 2. BEFORE YOU TAKE CLOPIXOL

### Do not take Clopixol

- If you are allergic (hypersensitive) to zuclopenthixol or any of the other ingredients of Clopixol (see What Clopixol contains)
- If you have diminished consciousness

### Take special care with Clopixol

- If you have a liver problem
- If you have a history of convulsions or fits
- If you have diabetes (you may need an adjustment of your antidiabetic therapy)
- If you have an organic brain syndrome (which may be a resulting condition after poisoning with alcohol or organic solvents)
- If you have risk factors for stroke (e.g. smoking, hypertension)
- If you have hypokalemia or hypomagnesia (too little potassium or magnesium in your blood) or genetic predisposition for any of these
- If you have a history of cardiovascular disorders
- If you use other antipsychotic medicine
- 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

Please consult your doctor, even if these statements were applicable to you at any time in the past.

### Taking other medicines

Some medicines may affect the action of another and this can sometimes cause serious adverse reactions.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

- Tricyclic antidepressant medicines
- Guanethidine and similar medicines (used to lower the blood pressure)
- Barbiturates and similar medicines (make you feel drowsy)
- Medicines used to treat epilepsy
- Levodopa and similar medicines (used to treat Parkinson's disease)
- Metoclopramide (used in the treatment of gastro-intestinal disorders)
- Piperazine (used in the treatment of roundworm and threadworm infection)
- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of Clopixol in your blood

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

- Medicines that change the heartbeat (e.g. quinidine, amiodarone, sotalol, dofetilide, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines (e.g. thioridazine)

### Taking Clopixol with food and drink

Clopixol can be taken with or without food.

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

### Pregnancy

Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant or think you may be pregnant, tell your doctor. Clopixol should not be used during pregnancy, unless clearly necessary. The general condition of your newborn baby might be affected by the use of this medicine.

## Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

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

### Driving and using machines

There is a risk of feeling drowsy and dizzy when using Clopixol, especially in the beginning of the treatment. If this happens do not drive or use any tools or machines until these effects wear off.

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

This medicinal product contains lactose. If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicinal product contains hydrogenated castor oil, which may cause stomach upset and diarrhoea.

## 3. HOW TO TAKE CLOPIXOL

### How much to take

Always take Clopixol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The dose varies considerably and depends on the severity of the illness.

#### Adults

#### *Schizophrenia, mania, and other psychoses*

The starting dose is usually between 10 mg and 50 mg per day. This dose may gradually be increased to 75 mg per day.

In some cases a considerably higher dose may be necessary. The maximum dose is 150 mg per day.

The maintenance dose is usually 20-40 mg per day.

#### *Agitation in mentally handicapped patients*

The dose is usually between 6 mg and 20 mg per day. If necessary the dose may be increased to 25-40 mg per day.

#### *Children*

Clopixol is not recommended for children.

#### *Patients with special risks*

Patients with liver complaints normally receive doses in the lower end of the dosage range.

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

### How and when to take Clopixol

Clopixol can be taken with or without food. Swallow the tablets with a drink of water. Do not chew them.

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.

### Duration of treatment

Like for other medicines for psychoses it may take a couple of weeks before you start to feel better.

Your doctor decides the duration of treatment. Continue to take the tablets for as long as your doctor recommends. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Never change the dose of the medicine without talking to your doctor first.

### If you take more Clopixol than you should

If you think that you or anyone else may have taken too many Clopixol tablets contact your doctor or nearest hospital casualty department immediately. Do this even if there are no signs of discomfort or poisoning. Take the Clopixol container with you if you go to a doctor or hospital.

Symptoms of overdose may include:

- Drowsiness
- Unconsciousness
- Muscle movements or stiffness
- Convulsions
- Low blood pressure, weak pulse, fast heart rate, pallor, restlessness
- High or low body temperature
- Changes in the heartbeat including irregular heartbeat or slow heart rate has been seen when Clopixol has been given in overdose together with medicines known to affect the heart

### If you forget to take Clopixol

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

### If you stop taking Clopixol

Your doctor will decide when and how to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped abruptly (e.g. difficulty in sleeping, muscle stiffness, feeling unwell).

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. POSSIBLE SIDE EFFECTS

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

### **If you experience any of the following symptoms you should contact your doctor or go to the hospital straight away:**

Uncommon (in more than 1 out of 1,000 and less than 1 out of 100 persons):

- Unusual movements of the mouth and tongue; this may be an early sign of a condition known as tardive dyskinesia

Very rare (in less than 1 out of 10,000 persons):

- High fever, unusual stiffness of the muscles and disorder of your consciousness, especially if occurring with sweating and fast heart rate; these symptoms may be signs of a rare condition called neuroleptic malignant syndrome which has been reported with the use of different antipsychotics
- Yellowing of the skin and the white in the eyes, this may mean that your liver is affected and a sign of a condition known as jaundice

**The following side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment.**

Very common (in 1 or more out of 10 persons):

- Sleepiness (somnolence), inability to sit still or remain motionless (akathisia), involuntary movements (hyperkinesia), slow or diminished movements (hypokinesia)
- Dry mouth

Common (in more than 1 out of 100 persons and less than 1 out of 10 persons):

- Racing heart (tachycardia), a sensation of a rapid, forceful, or irregular beating of the heart (palpitations)
- Tremor, twisting or repetitive movements or abnormal postures due to sustained muscle contractions (dystonia), increased muscle stiffness (hypertonia), dizziness, headache, sensation of tingling, pricking or numbness of the skin (paraesthesia), disturbance in attention, amnesia, gait abnormal
- Difficulties focusing on objects near to the eye (accommodation disorder), vision abnormalities
- Sensation of spinning or swaying while the body is stationary (vertigo)
- Blockage of the nasal passages (Nasal congestion), difficulty breathing or painful breathing (dyspnoea)
- Increased saliva secretion (salivary hypersecretion), constipation, vomiting, digestive problems or discomfort centered in the upper abdomen (dyspepsia), diarrhoea
- Urination disorder (micturition disorder), lack of ability to urinate (urinary retention), increased urination volume (polyuria)
- Increased sweating (hyperhidrosis), itching (pruritus)
- Muscle pain (myalgia)
- Increased appetite, increased weight
- Fatigue, weakness (asthenia), general feeling of discomfort or uneasiness (malaise), pain
- Sleeplessness (insomnia), depression, Anxiety, nervousness, abnormal dreams, agitation, decreased sexual drive (libido decreased)

Uncommon (in more than 1 out of 1,000 and less than 1 out of 100 persons):

- Overactive or overresponsive reflexes (hyperreflexia), jerky movements (dyskinesia), parkinsonism, fainting (syncope), inability to coordinate muscle activity (ataxia), speech disorder, decreased muscle tone (hypotonia), convulsion, migraine
- Circular movement of the eye (oculogyration), dilated pupils (mydriasis)
- Over-sensitivity to certain frequency ranges of sound or difficulty tolerating everyday sounds (hyperacusis), ringing in the ears (tinnitus)
- Abdominal pain, nausea, flatulence
- Rash, skin reaction due to sensitivity to light (photosensitivity reaction), pigmentation disorder, greasy, shiny and yellowish skin due to increased secretion of sebum (seborrhoea), eczema or inflammation of the skin (dermatitis), bleeding underneath the skin seen by red or purple discolorations on the skin (purpura)
- Muscle rigidity, inability to normally open the mouth (trismus), twisting of the neck and an unnatural position of the head (torticollis, wryneck, stiff neck)
- Decreased appetite, decreased weight
- Low blood pressure (hypotension), hot flush
- Thirst, abnormal low body temperature (hypothermia), fever (pyrexia)
- Abnormal liver function tests
- Sexual disturbance (delayed ejaculation, problems with erection, women may experience failure to achieve an orgasm, vaginal dryness (vulvovaginal dryness))
- Pronounced indifference to one's surroundings (apathy), nightmare, increased sexual drive (libido increased), state of confusion

Rare (more than 1 out of 10,000 and less than 1 out of 1,000 persons):

- Low blood platelet count (thrombocytopenia), low white blood platelet count (neutropenia), reduced white blood cell count (leukopenia), bone marrow poisoning (agranulocytosis)
- Increased level of prolactin in the blood (hyperprolactinaemia)
- High blood sugar (hyperglycaemia), impaired glucose tolerance, increased blood fat levels (hyperlipidaemia)
- Over-sensitivity (hypersensitivity), acute systemic and severe allergic reaction (anaphylactic reaction)
- Development of breasts in men (gynaecomastia), excessive milk production (galactorrhoea), lack of menstrual period (amenorrhoea), persistent, painful erection of the penis unaccompanied by sexual excitation or desire (priapism)

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:

- QT prolongation (slow heart beat and change in the ECG)
- Irregular heart beat (ventricular arrhythmias, ventricular fibrillation, ventricular tachycardia)
- Torsades de Pointes (a special kind of irregular heart beat)

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

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.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## 5. HOW TO STORE CLOPIXOL

Keep out of the reach and sight of children.

Do not use Clopixol after the expiry date, which is stated on the label or carton.

The expiry date refers to the last day of that month.

2 mg: Do not store above 25°C.

10 mg, 25 mg: Do not store above 30°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## 6. FURTHER INFORMATION

### What Clopixol contains

The active substance is zuclopenthixol (as dihydrochloride). Each Clopixol film-coated tablet contains 2 mg, 10 mg or 25 mg zuclopenthixol as hydrochloride salt.

The other ingredients are potato starch, lactose monohydrate, microcrystalline cellulose, copovidone, glycerol 85%, talc, hydrogenated castor oil and magnesium stearate.

Coating: Hypromellose 5 and macrogol 6000.

Colours: Titanium dioxide (E 171) and red iron oxide (E 172).

### What Clopixol looks like and contents of the pack

Clopixol is presented as 2 mg, 10 mg and 25 mg film-coated tablets.

Description of Clopixol film-coated tablets

The 2 mg film-coated tablets are round, biconvex, pale red.

The 10 mg film-coated tablets are round, biconvex, light red-brown.

The 25 mg film-coated tablets are round, biconvex, red-brown.

Clopixol film-coated tablets are available in blister packs or containers:

2 mg: 50, 100 and 250 film-coated tablets.

10 mg: 30, 50, 60, 100 and 250 film-coated tablets.

25 mg: 20, 30, 50, 60, 100 and 250 film-coated tablets.

Not all pack sizes may be marketed in your country.

### Marketing Authorisation Holder and Manufacturer

H. Lundbeck A/S

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### This leaflet was approved

May 2012