PIL0561.2
Package leaflet: Information for the user

# Clopixol® 10mg film-coated tablets

(zuclopenthixol dihydrochloride)

This medicine is known by the above name but will be referred to throughout this leaflet as Clopixol Tablets. Other strengths are also available.

**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, 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 possible side effects not listed in this leaflet. See section 4.

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## 1. What Clopixol Tablets are and what they are used for

Clopixol Tablets contain the active substance zuclopenthixol and belong 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 Tablets are used for the treatment of schizophrenia and other psychoses.

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

## 2. What you need to know before you take Clopixol Tablets

**Do not take Clopixol Tablets**
- If you are allergic to zuclopenthixol, other thioxanthene drugs or antipsychotic drugs or any of the other ingredients of this medicine (listed in section 6).
- 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 of nurse before taking Clopixol Tablets:
- 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 medicines like these have been associated with formation of blood clots

**Children and adolescents**
Clopixol is not recommended in these patients.

**Other medicines and Clopixol Tablets**
Tell your doctor or pharmacist if you are taking, have taken or might take any other medicines.

The following medicines should not be taken at the same time as Clopixol Tablets:
- 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 Tablets can reduce the effect of adrenaline (epinephrine) and similar drugs.

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

**Clopixol Tablets with food, drink and alcohol**
Clopixol Tablets can be taken with or without food.

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

**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 or pharmacist for advice before taking this medicine.

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

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

**Clopixol Tablets contain lactose and hydrogenated castor oil**
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Hydrogenated castor oil may cause stomach upset and diarrhoea.

## 3. How to take Clopixol Tablets

Always take Clopixol Tablets exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The dose varies and depends on the severity of the illness. The total amount of tablets you need to take each day will be split into at least two doses (for example a morning and evening dose).

**Adults**
Daily doses of Clopixol Tablets range from 4 mg to 150 mg.
The daily dose at the start of treatment is usually 20 mg to 30 mg each day.
This dose is then usually adjusted to between 20 mg and 50 mg each day.

The maximum dosage per single dose is 40 mg.

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

**Older patients (above 65 years of age)**
The initial dose is between a quarter and a half of the adult dose.

**Use in children**
Clopixol Tablets are not recommended for children.

How to take Clopixol Tablets
Swallow the tablets with a drink of water. Do not chew them.

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

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

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 take more Clopixol Tablets 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
- Fits
- Low blood pressure, weak pulse, fast heart rate, pale skin, restlessness
- High or low body temperature
- Changes in heart beat including irregular heart beat or slow heart rate

**If you forget to take Clopixol Tablets**
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 tablet.

**If you stop taking Clopixol Tablets**
Your doctor will decide how and when to stop your treatment to avoid any unpleasant symptoms that might occur if it is stopped abruptly (eg difficulty in sleeping, muscle stiffness, feeling unwell).

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

## 4. Possible side effects

Like all medicines, this medicine 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 taking Clopixol Tablets 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 Tablets 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 in 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)
- 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
- 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 Tablets), 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 via the Yellow Card Scheme at: Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

## 5. How to store Clopixol Tablets

- **Keep out of the sight and reach of children.**
- Do not use this medicine after the expiry date that is printed on the label. The expiry date refers to the last day of that month.
- These medicinal products do not require any special storage conditions.

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.

If your tablets become discoloured or show any signs of deterioration, return them to your pharmacist.

## 6. Contents of the pack and other information

**What Clopixol Tablets contain**
Each film-coated tablet contains 10mg zuclopenthixol (as dihydrochloride).
The other ingredients are potato starch, lactose monohydrate, microcrystalline cellulose, copolyvidone, glycerol 85%, talc, hydrogenated castor oil, magnesium stearate.
Film-coat: hypromellose 5, macrogol 6000.
Colour: titanium dioxide (E171), red iron oxide (E172), magnesium stearate.

**What Clopixol Tablets look like and contents of the pack**
Description of Clopixol Tablets: round, biconvex, light red-brown.

Clopixol Tablets are available in plastic containers containing 100 tablets.

**Manufactured by:**
H. Lundbeck A/S
Ottiliavej 9
DK-2500 Valby
Denmark.

**Procured from within the EU and repackaged by PL Holder:**
PilsCo Ltd., 10-16 Colvilles Place, East Kilbride, G75 0SN.

**PL 39467/0561**
**Clopixol® 10mg film-coated tablets**

**POM**

# Blind or partially sighted? Is this leaflet hard to see or read? Call 01355 711697 to obtain the leaflet in a format suitable for you.

**Leaflet last revised: 11/07/2022**.

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