CLOPIXOL® ORAL DROPS, SOLUTION

Zuclopenthixol, as hydrochloride (20mg/ml)

What is in this leaflet

What Clopixol is 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.

How Clopixol works

Clopixol contains the active substance zuclopenthixol. 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.

Before you use Clopixol

When you must not use it

Do not take Clopixol

- If you are allergic (hypersensitive) to zuclopenthixol or any of the other ingredients of this medicine (listed in section Ingredients).
- If you have diminished consciousness.

Before you start to use it

Talk to your doctor or pharmacist before taking Clopixol if you:

- Have a history of liver problem
- have a history of convulsions or fits
- have diabetes (you may need an adjustment of your antidiabetic therapy)
- have an organic brain syndrome (which may be a resulting condition after poisoning with alcohol or organic solvents)
- have risk factors for stroke (e.g. smoking, hypertension)
- have hypokalemia or hypomagnesia (too little potassium or magnesium in your blood) or genetic predisposition for any of these
- have a history of cardiovascular disorders
- Use other antipsychotic medicine.
- 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 adolescent
Clopixol is not recommended in this patient group.

Taking other medicines

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

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.

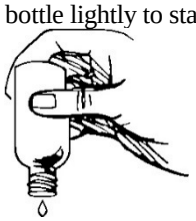
The following medicines should not be taken at the same time as Clopixol:

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

Clopixol with food and drink
Clopixol can be taken with or without food. The oral drops can be taken in water, orange juice or apple juice.
Clopixol may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment with Clopixol.

How to use Clopixol

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



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.

How much to use
Adults
Schizophrenia, mania, and other psychoses

CLOPIXOL® ORAL DROPS, SOLUTION

Zuclopenthixol, as hydrochloride (20mg/ml)

The starting dose is usually between 10 mg (10 oral drops) and 50 mg (50 oral drops) per day. This dose may gradually be increased to 75 mg (75 oral drops) per day.
In some cases a considerably higher dose may be necessary. The maximum dose is 150 mg (150 oral drops) per day.
The maintenance dose is usually 20-40 mg (20-40 oral drops) per day.

Agitation in mentally handicapped patients
The dose is usually between 6 mg (6 oral drops) and 20 mg (20 oral drops) per day. If necessary the dose may be increased to 25-40 mg (25-40 oral drops) per day.

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

Use in children
Clopixol is not recommended for children.
If you have the impression that the effect of Clopixol is too strong or too weak, talk to your doctor.

When to use it
Count the required number of oral drops into your drink (water, orange juice or apple juice), stir it briefly and then drink all of it.
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.

How long to use it
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 oral drops 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 forget to use it
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 use too much (overdose)
If you think that you or anyone else may have taken too many Clopixol oral drops 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.

While you are using it
Things you must do
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Things you must not do
- 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.

Things to be careful of
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 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 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 you doctor for advice. You should not use Clopixol when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility
Animal studies have shown that Clopixol affects the fertility. Please ask your doctor for advice.

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.

Clopixol oral drops contains ethanol
This medicinal product contains 14.2 vol % ethanol (alcohol), i.e. up to 240 mg per dose, equivalent to 5 ml beer, or 2 ml wine per dose. Harmful for those suffering from alcoholism.
To be taken into account in pregnant or breast-feeding women, children and high-risk groups such

CLOPIXOL® ORAL DROPS, SOLUTION

Zuclopenthixol, as hydrochloride (20mg/ml)

as patients with liver disease, or epilepsy.

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

CLOPIXOL® ORAL DROPS, SOLUTION

Zuclopenthixol, as hydrochloride (20mg/ml)

(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 periods (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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public --> Reporting Medicinal Problems / Side Effects / AEFI)

Storage and Disposal of Clopixol
Storage
Keep this medicine out of the reach and sight of children. Store below 25°C. After first opening, Clopixol oral drops are valid for 6 weeks when stored below 25ºC. Keep the bottle in the outer box in order to protect from light.

Disposal
Do not use this medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month. 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.

Product Description
What it looks like
It is a clear, nearly colourless to yellowish solution without odour and with a slightly bitter taste.

Clopixol oral drops are available in dropper containers (bottles) of 10 and 20 ml.

Ingredients
- Active ingredient: The active substance is zuclopenthixol (as hydrochloride). Each millilitre (ml) of Clopixol oral drops contains 20 mg zuclopenthixol. 1 drop = 1 mg zuclopenthixol.
- Inactive ingredient: The other ingredient is ethanol 96 per cent, purified water. The oral drops contain 14.2 Vol% alcohol (120 mg per ml).

MAL No.: MAL19890539AZ

Manufacturer
H. Lundbeck A/S
Ottiliavej 9
2500 Valby
Denmark

Product Registration Holder
Lundbeck Malaysia Sdn. Bhd.
A-05-01, Oasis Square
Jalan PJU 1A/7A, Ara Damansara
47301 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Date of Revision
25/05/2018

Serial Number
NPRA (R1/1) 22052018/056