

PACKAGE LEAFLET: INFORMATION FOR THE USER

Clopixol 10 mg film-coated tablets. (zuclopenthixol dihydrochloride)

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Clopixol is and what it is used for
2. What you need to know before you take Clopixol
3. How to take Clopixol
4. Possible side effects
5. How to store Clopixol
6. Contents of the pack and other information

1. What Clopixol is and what it is used for

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.

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

Ask your doctor if you have any questions about why Clopixol has been prescribed for you.

2. What you need to know before you take Clopixol

Do not take Clopixol

- if you are allergic to zuclopenthixol or any of the other ingredients of this medicine (listed in section 6). Consult your doctor if you think you might be.
- if you have a reduced level of alertness due to any cause (this includes reduced alertness after the consumption of alcohol or drugs such as opiates (e.g. morphine) and barbiturates)
- if you are an older person who suffers from confusion
- if you are receiving emergency treatment to support your blood circulation
- if you are a child
- if you are unconscious (in a coma)

Warnings and precautions

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

- have a liver problem

- have a history of fits or convulsions or have any condition that might make you prone to fits e.g. head injury, alcohol withdrawal
- are an older person (you may be at risk of low body temperature, sedation, low blood pressure or confusion)
- have dementia
- have Parkinson's disease
- have a narrow angle glaucoma (or a family history of this condition)
- have a respiratory disease (e.g. asthma or COPD (chronic obstructive pulmonary disease))
- have diabetes (you may need an adjustment of your diabetes therapy)
- have a history of drug or alcohol abuse
- have a brain injury or disease
- have a mental retardation
- have risk factors for stroke (e.g. hardening of the arteries, smoking, hypertension)
- were born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning) e.g. significantly lowered or irregular heart beat or any other heart condition (e.g. a heart attack)
- or someone else in your family has a heart condition
- are taking medicines that change the heartbeat or if you have hypokalaemia or hypomagnesaemia (too little potassium or magnesium in your blood)
- suffer from an under or over active thyroid, myasthenia gravis (a condition causing severe muscular weakness) or an enlarged prostate.
- are about to undergo any procedure which will require a general anaesthetic (if this is for dentistry, tell your dentist)
- use other antipsychotic medicine
- are more excited or overactive than normal
- are on long-term therapy (particularly with high dosage). Your doctor will review your treatment to decide whether the current dose can be lowered.
- 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 this patient group.

Other medicines and Clopixol

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 (e.g. amitriptyline, imipramine)
- Guanethidine, hydralazine and similar medicines (used to lower 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)
- Digoxin (used in the treatment of heart conditions)
- Corticosteroids (used to treat a range of conditions, including inflammatory diseases)
- Warfarin, ticlopidine, dipyridole and similar medicines called anticoagulants (used to thin the blood)

- Medicines such as diuretics (water tablets) that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known as non steroidal anti-inflammatory drugs (NSAIDs e.g. ibuprofen, diclofenac, mefenamic acid) and aspirin which are used to relieve pain and to thin the blood)
- Medicines known as phenothiazines used to treat mental illness (e.g. chlorpromazine, fluphenazine)
- Medicines known as neuromuscular blocking agents (e.g. suxamethonium) as concomitant treatment with Clopixol may prolong the effect of neuromuscular blocking agents
- Adrenergic medicines (e.g. atenolol) as concomitant treatment with Clopixol may reduce the effect of adrenergic medicines)

The following medicines should not be taken with Clopixol:

- Medicines for heart rhythm problems such as medicines used to treat irregular heartbeats (e.g. quinidine, amiodarone, sotalol, dofetilide), certain antibiotics (erythromycin, gatifloxacin, moxifloxacin), certain antihistamines (e.g. astemizole, terfenadine), and other medicines such as cisapride and lithium
- Other antipsychotic medicines (e.g. thioridazine)

Clopixol with food, drink and alcohol

Clopixol can be taken with or without food.

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might 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 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 your 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 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 film-coated 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

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.

The recommended dose is:

Adults

The usual starting dose is 20-30 mg/day. This dose may gradually be increased to 150 mg/day. The usual maintenance dose in chronic schizophrenia is 20-50 mg/day in divided doses.

Older people (above 65 years)

Older people are usually treated with doses in the lower end of the dosage range.

Use in children and adolescents

Clopixol is not recommended for children and adolescents.

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

Swallow the tablets with a drink of water. Do not chew them.

The total daily dose of Clopixol is usually taken in divided doses.

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.

Side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment:

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

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

- Racing heart, a sensation of a rapid, forceful, or irregular beating of the heart

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

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

Rare (may affect up to 1 in 1,000 people):

- Low blood platelet count. A common symptom is bruising of the skin. Low white blood cell count. Symptoms could be increased frequency of infections. Severe reduction in the number of white blood cells which makes infections more likely.
- Hypersensitivity, acute systemic and severe allergic reaction. Most severe allergic reactions involve the skin with development of hives, generalized redness and swelling of face, eyelids, lips, tongue, throat, hands, and feet. Other symptoms could be difficulty breathing, wheezing, chest tightness, rapid heart beat, dizziness and loss of consciousness. The symptoms of severe allergic reactions can vary. In some people, the reaction begins very slowly, but in most the symptoms appear rapidly and abruptly
- Persistent, painful erection of the penis unaccompanied by sexual excitation or desire.

Very rare (may affect up to 1 in 10,000 people):

- High fever, unusual stiffness of the muscles and altered mental status 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.
- 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.

The following side effects have also been reported:

Very common (may affect more than 1 in 10 people):

- Sleepiness, inability to sit still or remain motionless, involuntary movements, slow or diminished movements
- Dry mouth

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

- Tremor, twisting or repetitive movements or abnormal postures due to sustained muscle contractions, increased muscle stiffness, dizziness, headache, sensation of tingling, pricking or numbness of the skin, disturbance in attention, amnesia, difficulty in walking
- Difficulties focusing on objects near to the eye, vision abnormalities
- Sensation of spinning or swaying while the body is stationary
- Blockage of the nasal passages, difficulty breathing or painful breathing
- Increased saliva secretion, constipation, vomiting, digestive problems or discomfort centred in the upper abdomen, diarrhoea
- Urination disorder, lack of ability to urinate, increased urination volume
- Increased sweating, itching
- Muscle pain
- Increased appetite, increased weight
- Fatigue, weakness, general feeling of discomfort or uneasiness, pain
- Insomnia, depression, anxiety, nervousness, abnormal dreams, agitation, decreased sexual drive

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

- Overactivity in the nerves which control muscles, jerky movements, tremor and difficulty in controlling movements, fainting, inability to coordinate muscle activity, speech disorder, decreased muscle tone, convulsion, migraine
- Circular movement of the eye, dilated pupils

- Over-sensitivity to certain frequency ranges of sound or difficulty tolerating everyday sounds, ringing in the ears
- Abdominal pain, nausea, flatulence
- Rash, skin reaction due to sensitivity to light, pigmentation disorder, greasy, shiny and yellowish skin due to increased secretion of sebum, eczema or inflammation of the skin, bleeding underneath the skin seen by red or purple discolorations on the skin
- Muscle rigidity, inability to normally open the mouth, twisting of the neck and an unnatural position of the head
- Decreased appetite, decreased weight
- Low blood pressure, hot flush
- Thirst, abnormally low body temperature, fever
- Abnormal liver function tests
- Sexual disturbance (delayed ejaculation, problems with erection, women may experience failure to achieve an orgasm, vaginal dryness)
- Pronounced indifference to one's surroundings, nightmare, increased sexual drive, state of confusion

Rare (may affect up to 1 in 1,000 people):

- High blood sugar, impaired glucose tolerance, increased blood fat levels. Often there are no symptoms. Hyperglycaemia over long time could show as fatigue, weight loss, excessive thirst and urination.
- Increased level of prolactin in the blood. Symptoms of hyperprolactinaemia could be excessive milk production, lack of menstrual periods and development of breasts in men.

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:

- Slow heart beat and change in the ECG
- Irregular heart beat
- Torsade de Pointes (a special kind of irregular heart beat)

In rare cases irregular heart beats 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.

If you stop taking Clopixol too quickly, you may experience discontinuation symptoms. The most common discontinuation symptoms are nausea, vomiting, loss of appetite, diarrhoea, runny nose, sweating, pains in the muscles, feelings like pins and needles, insomnia, restlessness, anxiety or agitation. You may also experience dizziness, alternative feelings of warmth and coldness and shakiness. The symptoms usually begin within 1 to 4 days of stopping Clopixol and go away within 7 to 14 days. If you get severe discontinuation symptoms, contact your doctor for advice.

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 HPRAPharmacovigilance, website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Clopixol

Keep this medicine out of the sight and reach of children.

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

This medicine does not require any special temperature storage conditions.

Store in the original package and keep the bottle tightly closed in order to protect from moisture.

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. Contents of the pack and other information

What Clopixol contains

The active substance is zuclopenthixol (as dihydrochloride).

Each Clopixol film-coated tablet contains 10 mg zuclopenthixol as dihydrochloride salt.

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

Coating: Hypromellose 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 10 mg film-coated tablets (tablets).

Description of Clopixol film-coated tablets

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

Clopixol film-coated tablets are available in polypropylene or high density polyethylene (HDPE) containers containing 100 tablets.

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