Clopixol® (clo-PIK-sol)

Clopixol® Tablets 10 mg
Clopixol® Acuphase Injection 50 mg/mL
Clopixol® Depot Injection 200 mg/mL

Zuclopenthixol hydrochloride (zoo-clo-PEN-thic-sol high-dro-CLOR-ride)
Zuclopenthixol acetate (zoo-clo-PEN-thic-sol AS-se-tate)
Zuclopenthixol decanoate (zoo-clo-PEN-thic-sol deck-can-OH-ate)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet contains answers to some common questions about Clopixol.

It does not contain all the information that is known about Clopixol. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What Clopixol is used for

Clopixol tablets are used for the acute and long-term treatment of schizophrenia and other mental illnesses with disturbances in thinking, emotional reactions and behaviour.

It is also used to treat the manic phase of manic depressive illness. A manic phase is a mood of excitement, over-activity and uninhibited behaviour.

Clopixol Acuphase injection is used for the initial treatment of acute episodes of mental disorders. It is also used to treat mania (a mental condition characterised by episodes of overactivity, elation or irritability) and used in case of worsening of chronic mental conditions.

Clopixol Depot injection is usually used to prevent further episodes of your illness.

Clopixol belongs to a group of medicines called thioxanthene neuroleptics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

Your doctor, however, may prescribe it for another purpose.

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

This medicine is only available with a doctor's prescription.

Clopixol is not addictive.

Before you use it

When you must not use it

Do not use Clopixol if you are allergic to it, to any other similar medicines (such as thioxanthenes or phenothiazines), or any of the ingredients listed at the end of this leaflet.
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

Do not use Clopixol if you have:
- collapse due to very low blood pressure
- diminished consciousness due to any cause
- brain damage
- diseases of the blood with abnormal or reduced number of red or white blood cells or platelets
- phaeochromocytoma, a rare tumour of the adrenal gland which sits near the kidney.

Do not give Clopixol to anyone who currently has alcohol poisoning, or poisoning with medicines used to produce calmness or to help you sleep, or medicines used to treat epilepsy or strong pain.

Do not give Clopixol to anyone who is unconscious or in a coma.

Do not use it after the expiry date printed on the pack.
If you use it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

Do not use it if the packaging is torn or shows signs of tampering.

Before you start to use it

Tell your doctor if:

1. **you have allergies to any other substances such as foods, preservatives or dyes.**
2. **you are pregnant or intend to become pregnant.**

   Clopixol may affect your fertility. If you are intending to start a family, ask your doctor for advice.

   Like most medicines of this kind, Clopixol is not recommended for use during pregnancy unless clearly necessary. The general condition of your baby might be affected by the use of this medicine.

   The following symptoms may occur in newborn babies of mothers who have used Clopixol in the 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 should contact your doctor.
3. **you are breast-feeding or planning to breast-feed.**

   It is not recommended that you breast-feed while using Clopixol. Its active ingredient passes into breast milk and therefore there is a possibility that your baby might be affected.
4. **you have, or have had, the following medical conditions:**
   - arteriosclerosis, a disease affecting the arteries
   - convulsions, fits or seizures
   - decreased blood supply to the brain
   - diabetes, a disorder of metabolism in which the amount of sugar in the blood is too high
   - feeling lethargic, indifferent, lost or remote
   - glaucoma, a condition in which there is usually a build-up of pressure in the eye
   - heart and blood vessel problems
   - kidney problems
   - liver problems
   - low potassium and/or low magnesium levels in the blood
   - organic brain syndrome
   - parkinsonism, a disease of the brain affecting movement
   - risk factors for stroke
   - tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs.
   - treatment for cancer
   - 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
   - sleep apnoea (a sleep disorder where your breathing is interrupted during sleep).

Also tell your doctor if you will be in a hot environment or you do a lot of vigorous exercise.
Clopixol may make you sweat less, causing your body to overheat.

Tell your doctor if you are exposed to pesticides that contain phosphorus.
The risk of you experiencing a side effect may be increased.

If you are lactose intolerant, contact your doctor before taking Clopixol tablets.
Clopixol tablets contain lactose.

Do not give Clopixol to a child or adolescent.
There is no experience with its use in children or adolescents under 18 years old.

If you have not told your doctor about any of the above, tell them before you use Clopixol.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.
Some medicines and Clopixol may interfere with each other. These include:

- tricyclic antidepressants and lithium, medicines used to treat depression or mood swings
- medicines used to treat strong pain
- medicines used to produce calmness or to help you sleep
- medicines used to treat high blood pressure (hypertension), such as guanethidine
- levodopa, a medicine used to treat Parkinson's disease
- medicines which stimulate the body, getting it ready for action, such as adrenaline
- metoclopramide, a medicine used to relieve nausea and vomiting
- piperazine, a medicine used to treat worm infections
- medicines known to inhibit the activity of certain liver enzymes
- medicines used to treat changes in the rhythm or rate of the heart beat, e.g. quinidine, amiodarone, sotalol and dofetilide
- antipsychotics, a class of medicines used to treat certain mental and emotional conditions, e.g. thioridazine
- certain medicines used to treat infections, such as erythromycin, gatifloxacin and moxifloxacin
- medicines used to relieve the symptoms of allergy, including terfenadine and astemizole
- cisapride, used to treat stomach problems
- medicines that disturb water or salt balance e.g. thiazide diuretics, also called fluid or water tablets

- medicines known to increase the concentration of Clopixol in your blood
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease, such as atropine or related medicines.
- medicines used to treat cancer

These medicines may be affected by Clopixol, or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Clopixol.

How to use it

How much to use

Clopixol tablets
The usual dose is 10 to 50 mg per day.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.
They will tell you exactly how much to take.

Follow the instructions they give you.
If you take the wrong dose, Clopixol may not work as well and your condition may not improve.

Clopixol Acuphase injection
The usual dose is 50 to 150 mg (1 to 3 mL) every 2 to 3 days or as instructed by your doctor.

The duration of the treatment should not be more than 2 weeks.

The maximum dose should not be more than 400 mg and the total number of injections should not be more than 4 per course of treatment.

Clopixol Depot injection
The usual dose is 200 to 400 mg (1 to 2 mL) every second to fourth week.

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and your response to the medicine. Generally, your doctor will start you on smaller doses which will be gradually increased until a dose is reached where Clopixol works best for you.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. Follow the instructions they give you.
They will tell you exactly how much you will be given.

Elderly patients
The dosage of Clopixol may need to be reduced in elderly patients.

How to use it

Clopixol tablets
Swallow the tablets whole with a full glass of water.

To open this child resistant bottle, please hold, twist and turn the bottle as per the diagram below.

Clopixol injections
Clopixol is given as an injection into a large muscle where it is slowly released over time. The injection should only be given by a doctor, nurse or other trained person.

When to use it

You may be given Clopixol tablets or injections which both have the same effects on your illness, although they last for different lengths of time.

Clopixol tablets
Clopixol tablets only work for a short time, so they need to be taken every day.

Take Clopixol tablets once a day at about the same time.
Taking them at the same time each day will also help you remember when to take the tablets.

Take Clopixol tablets before or after food.

Clopixol injections
Clopixol Acuphase injection has to be given every 2 - 3 days, while Clopixol Depot injection lasts several weeks, so it is given once every 2 - 4 weeks.

Your doctor will advise you.

How long to use it

Continue taking your tablets and/or having your injections for as long as your doctor tells you to.
Clopixol helps control your condition, but does not cure it. Therefore, you will need regular treatment.

If you forget to use it

Clopixol tablets

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If there is still a long time to go before your next dose, take it as soon as you remember, and then go back to taking it as you would normally.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

Clopixol injections

If you forget to keep an appointment, contact your doctor as

soon as you remember, so that you can make another one.

Overdose

Immediately telephone your doctor, or the National Poisons Centre (Tel: 0800 764 766 for New Zealand), or go to Accident and Emergency at your nearest hospital, if

- **you think you or anyone else may have taken too many Clopixol tablets. Do this even if there are no signs of discomfort or poisoning.**
- **you experience any side effects after being given Clopixol injections.**

You may need urgent medical attention.

As Clopixol injections are given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

Symptoms of an overdose may include sleepiness, coma, cramps, convulsions, low blood pressure and extremely high or low body temperature. Uncontrollable movements may develop, and collapse due to very low blood pressure may occur. Changes in the rhythm or rate of the heart beat have been seen in Clopixol overdose when medicines known to affect the heart have also been taken.

While you are using it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Clopixol.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you become pregnant while using Clopixol, tell your doctor immediately.

Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.
These are symptoms of a condition called tardive dyskinesia, which may develop in people taking similar medicines, including Clopixol.

This condition is more likely to occur during long-term treatment with Clopixol, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

Also tell your doctor if you notice any soreness of the mouth, gums, throat or other flu-like symptoms.

Talk to your doctor or mental health professional if you are thinking or talking about death, suicide, self-harm or harm to others.

These may be signs of changes or worsening in your mental illness.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.
Clopixol may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are using this medicine.
It may interfere with the results of some tests.

Protect your skin when you are in the sun, especially between 10am and 3pm.

If you are outdoors, wear protective clothing and use a 30+ sunscreen.

If your skin appears to be burning, tell your doctor.
Clopixol may cause your skin to be much more sensitive to sunlight than it is normally. This could cause skin rash, itching, redness, or severe sunburn.

Keep all of your doctor's appointments so that your progress can be checked.
Your doctor may do some blood and liver tests from time to time, particularly during the first months of therapy, to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use Clopixol to treat any other complaints unless your doctor tells you to.

Do not take any medicines that cause drowsiness while you are using Clopixol, unless recommended by your doctor.

Do not stop using Clopixol, or lower the dosage, without checking with your doctor.

Do not miss any injections, even if you feel better.
Clopixol helps control your condition, but does not cure it. Therefore, you will need regular injections.

Do not stop using Clopixol suddenly.
If Clopixol is stopped suddenly, you may experience symptoms such as nausea, vomiting, loss of appetite, diarrhoea, runny nose, sweating, aching muscles, pins and needles, sleeplessness, restlessness, anxiety, or agitation.

Your doctor may want to gradually reduce the amount you are using before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Clopixol affects you.
It may cause drowsiness, tiredness, sleepiness or blurred vision in some people. If you have any of these symptoms, do not drive, operate

machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are using this medicine. If you drink alcohol, drowsiness or sleepiness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Clopixol. It helps most people with mental illness, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

Tell your doctor if you notice any of the following and they worry you:

- drowsiness, sleepiness
- inability to sleep
- abnormal dreams
- headache
- fatigue
- depressed mood
- anxiousness
- nervousness, agitation
- headaches
- nasal congestion
- dry mouth
- constipation or diarrhoea
- increased salivation or increased sweating
- nausea, vomiting, dyspepsia
- weight and appetite changes
- change in your menstrual periods
- impaired sexual function
- swelling of hands, ankles or feet
- skin rash, itching.
- abnormal sensations, such as burning or prickling
- changes in attention and memory
- dizziness or spinning sensation
- painful or weak muscles
- pain at the injection site
- feeling generally unwell

Tell your doctor immediately if you notice any of the following:

- sudden onset of unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, or shuffling walk and stiffness of the arms and legs
- worm-like movements of the tongue or other uncontrolled movements of the mouth, tongue, cheeks or jaws, which may progress to the arms and legs
- inability to keep still
- increased, slowed or unusual muscle movements
- feeling dizzy when standing up
- irregular heart beat and changes in heart rate and blood pressure
- fainting
- blurred vision or difficulty focusing
- difficulty passing urine
- increased urination or other urinary disorder
- high pressure in the eye
- unusual secretion of breast milk
- breast enlargement in men
- difficult or painful breathing
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nosebleeds
- yellowing of the skin and/or eyes, also called jaundice
- severe pain in the stomach with bloating, gut cramps and vomiting.
- 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.
- On rare occasions, neuroleptic malignant syndrome may lead to muscle breakdown (rhabdomyolysis). Symptoms include muscle pain, muscle weakness, and dark-coloured urine. If you notice any of these symptoms, seek medical advice immediately.
- Difficulty in swallowing may occur secondary to movement disorders, sedation, increased salivation and /or neuroleptic malignant syndrome (presented as high fever along with rigidity, altered consciousness or confusion or agitation and fast heartbeat).

These may be serious side effects of Clopixol. You may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives)
- sudden increase in body temperature, unusual stiffness of the muscles and changes in consciousness, especially in conjunction with fast heart rate and sweating. This may be due to a

very rare condition called neuroleptic malignant syndrome, which has been reported with various antipsychotic medicines.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are generally rare.

Tell your doctor if you notice anything else that is making you feel unwell.
Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

After using it

Storage

Keep Clopixol in the pack until it is time to use it.
If you take the tablets or the ampoules out of the pack they may not keep well.

Keep Clopixol away from sunlight.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.
Heat and damp can destroy some medicines.

Keep it where children cannot reach it.
A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine, or the expiry date has passed, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Clopixol comes as tablets and in two types of injections:

- Clopixol 10 mg film-coated tablets - light red brown, round biconvex tablets
- Clopixol Acuphase 50 mg/mL solution for injection - clear, yellowish oil
- Clopixol Depot 200 mg/mL solution for injection - clear, yellowish oil.

The tablets are available in bottles of 100 tablets and the injections come in boxes of 5 ampoules.

Ingredients

Active ingredient(s):

- Clopixol 10 mg tablets - 10 mg zuclopenthixol (as hydrochloride) per tablet
- Clopixol Acuphase 50 mg/mL injection - 50 mg zuclopenthixol acetate per 1 mL or 100 mg zuclopenthixol acetate per 2 mL
- Clopixol Depot 200 mg/mL injection - 200 mg zuclopenthixol decanoate per 1 mL.

Inactive ingredients (tablets):

- hydrogenated castor oil
- microcrystalline cellulose
- glycerol
- hypromellose
- iron oxide red
- lactose monohydrate
- macrogol 6000
- magnesium stearate
- copovidone
- potato starch
- purified talc
- titanium dioxide.

Clopixol tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Inactive ingredient (injections):

- fractionated coconut oil.

Manufacturer/Sponsor

Clopixol is made by H. Lundbeck A/S, Denmark.

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