

Clopixol®

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

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Clopixol?

Clopixol Tablet, Acuphase and Depot contain the active ingredient Zuclopenthixol hydrochloride, Zuclopenthixol acetate and Zuclopenthixol decanoate, respectively. Clopixol tablets are used for the acute and long-term treatment of schizophrenia and other mental illnesses, and to treat the manic phase of manic-depressive illness. Clopixol Acuphase injection is used for the initial treatment of acute episodes of mental disorders and to treat mania. Clopixol Depot injection is used to prevent further episodes of your illness. For more information, see Section [1. Why am I using Clopixol?](#) in the full CMI.

2. What should I know before I use Clopixol?

Do not use if you have ever had an allergic reaction to Zuclopenthixol hydrochloride, Zuclopenthixol acetate or Zuclopenthixol decanoate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Clopixol?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Clopixol and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Clopixol?

- Clopixol tablets: the usual dose is 10 to 50 mg per day; Clopixol Acuphase injection: the usual dose is 50 to 150 mg (1 to 3 mL) every 2 to 3 days; Clopixol Depot injection: the usual dose is 200 to 400 mg (1 to 2 mL) every second to fourth week.
- Clopixol tablets should be swallowed whole with a full glass of water; Clopixol injections should only be given by a doctor, nurse or other trained healthcare professional.

More instructions can be found in Section [4. How do I use Clopixol?](#) in the full CMI.

5. What should I know while using Clopixol?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Clopixol. • Protect your skin when you are in the sun, especially between 10am and 3pm. • Call your doctor straight away if you become pregnant while using Clopixol or notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw.
Things you should not do	• Do not stop using Clopixol, or lower the dosage, without checking with your doctor. • Do not take any medicines that cause drowsiness while you are using Clopixol.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Clopixol affects you.
Drinking alcohol	• Tell your doctor if you drink alcohol. • Be careful when drinking alcohol while you are using this medicine.
Looking after your medicine	• Keep Clopixol in the outer carton in order to protect from light. • Keep the medicine in a cool dry place where the temperature stays below 25°C.

For more information, see Section [5. What should I know while using Clopixol?](#) in the full CMI.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, contact your doctor or nurse.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Clopixol® (clo-PIK-sol)

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

Active ingredient(s): 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)

This leaflet provides important information about using Clopixol. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Clopixol.**

Where to find information in this leaflet:

1. [Why am I using Clopixol?](#)
2. [What should I know before I use Clopixol?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Clopixol?](#)
5. [What should I know while using Clopixol?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Clopixol?

Clopixol Tablet, Acuphase and Depot contains the active ingredients Zuclopenthixol hydrochloride, Zuclopenthixol acetate and Zuclopenthixol decanoate, respectively.

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

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.

2. What should I know before I use Clopixol?

Warnings

Do not use Clopixol if:

- you are allergic to ingredients Zuclopenthixol hydrochloride, Zuclopenthixol acetate or Zuclopenthixol decanoate, or any of the ingredients listed at the end of this leaflet.
 - o Always check the ingredients to make sure you can use this medicine.

- o 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.
- you have collapsed due to very low blood pressure
- you have diminished consciousness due to any cause
- you have brain damage
- you have diseases of the blood with abnormal or reduced number of red or white blood cells or platelets
- you have phaeochromocytoma, a rare tumour of the adrenal gland which sits near the kidney

Do not give Clopixol to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

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.

Check with your doctor if you:

- have allergies to any other substances such as foods, preservatives or dyes.
- take any medicines for any other condition
- you have, or have had, the following medical conditions:
 - o arteriosclerosis, a disease affecting the arteries
 - o convulsions, fits or seizures
 - o decreased blood supply to the brain
 - o diabetes, a disorder of metabolism in which the amount of sugar in the blood is too high
 - o feeling lethargic, indifferent, lost or remote
 - o glaucoma, a condition in which there is usually a build-up of pressure in the eye
 - o heart and blood vessel problems
 - o kidney problems
 - o liver problems
 - o low potassium and/or low magnesium levels in the blood
 - o organic brain syndrome
 - o parkinsonism, a disease of the brain affecting movement
 - o risk factors for stroke
 - o 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.

- o treatment for cancer
- o sleep apnoea (a sleep disorder where your breathing is interrupted during sleep)
- o 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

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.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Animal studies have shown that ClopiXol affects 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.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements 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 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ClopiXol.

4. How do I use ClopiXol?

How much to take / 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.

When to use Clopixol

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 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.

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.

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 Clopixol

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.

If you use too much Clopixol

If you think that you have used too much Clopixol, you may need urgent medical attention.

You should immediately:

- phone the **Poisons Information Centre (by calling 13 11 26 for Australia and Tel: 0800 764 766 for New Zealand)**, or
- contact your doctor, or
- go to **Accident and Emergency at your nearest hospital**, if
 - o you think you or anyone else may have taken too many Clopixol tablets.
 - o you experience any side effects after being given Clopixol injections.

You may need urgent medical attention.

You should do this even if there are no signs of discomfort or poisoning

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 heartbeat have been seen in Clopixol overdose when medicines known to affect the heart have also been taken.

5. What should I know while using Clopixol?

Things you should 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 Clopixol.

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.

Call your doctor straight away if you:

- become pregnant while using Clopixol.
- 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.

Things you should 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.

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.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

Drinking alcohol

Tell your doctor if you drink alcohol.

If you drink alcohol, drowsiness or sleepiness may be worse.

Be careful when drinking alcohol while you are using this medicine.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

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 in the outer carton in order to protect from light.

Store it in a cool dry place below 25°C away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

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.

When to discard your medicine

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.

Getting rid of any unwanted medicine

Return any unused medicine to your pharmacist.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• 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	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• 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	Tell your doctor straight away if you notice any of these serious side effects.

Serious side effects	What to do
(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.	
- 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.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What Clopixol contains

Active ingredient (main ingredient)	- 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.
Tablets Other ingredients (inactive ingredients)	hydrogenated castor oil microcrystalline cellulose glycerol hypromellose iron oxide red lactose monohydrate macrogol 6000 magnesium stearate copovidone potato starch purified talc titanium dioxide.
Injections Other ingredients (inactive ingredients)	fractionated coconut oil.
Potential allergens	Clopixol tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Do not take this medicine if you are allergic to any of these ingredients.

What Clopixol looks like

Clopixol is available as tablets and injections:

- Clopixol 10 mg film-coated tablets - light red brown, round biconvex tablets. (AUST R 45077)
- Clopixol Acuphase 50 mg/1 mL solution for injection - clear, yellowish oil. (AUST R 45080)
- Clopixol Acuphase 100 mg/2 mL solution for injection - clear, yellowish oil. (AUST R 46061)
- Clopixol Depot 200 mg/1 mL solution for injection - clear, yellowish oil. (AUST R 45082)

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

Who distributes Clopixol?

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

Distributed in Australia by:

Lundbeck Australia Pty Ltd

1 Innovation Rd

North Ryde NSW 2113

Ph: +61 2 8669 1000

Distributed in New Zealand by:

Healthcare Logistics

PO Box 62027

Mt Wellington, Auckland

Ph: +64 9 9185100

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