

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **CLOPIXOL**®

zuclopenthixol tablets

Pr **CLOPIXOL ACUPHASE**®

zuclopenthixol acetate injection

Pr **CLOPIXOL**® **DEPOT**

zuclopenthixol decanoate injection

This Patient Medication Information is written for the person who will be taking **CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT**, talk to a healthcare professional.

Serious warnings and precautions box

Risk of death in elderly patients with dementia:

- CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT belong to a group of medicines called antipsychotics. These medicines have been linked to a higher rate of death when used in elderly patients with dementia (loss of memory and other mental abilities).
- CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT are not to be used if you are elderly and have dementia.

Neuroleptic Malignant Syndrome (NMS): NMS is a rare but potentially life-threatening condition that has been reported with the use of antipsychotic medications like CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT. Symptoms include:

- severe muscle stiffness or inflexibility with high fever,
- rapid or irregular heartbeat,
- sweating,
- state of confusion or reduced consciousness

What CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT are used for:

CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT are used to treat symptoms of schizophrenia in adults. Not all people with this disorder have the same symptoms. Some of the most common symptoms of schizophrenia may include:

- hallucinations (seeing, feeling, hearing or smelling things that are not there)
- delusions (believing things that are not true)
- paranoia (not trusting others or feeling very suspicious)
- avoiding family members and friends and wanting to be alone

- feeling depressed, anxious or tense

CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT are not a cure for your condition, but they can help manage your symptoms and help you feel better.

How CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT work:

Antipsychotic medications affect the chemicals that allow your nerve cells to communicate with each other (neurotransmitters). Illnesses that affect the brain may be due to certain chemicals (dopamine and serotonin) in the brain being out of balance. These imbalances may cause some of the symptoms you may be experiencing. Exactly how CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT work is unknown. However, they seem to adjust the balance of these chemicals.

The ingredients in CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT are:

Medicinal ingredients:

- CLOPIXOL: zuclopenthixol (as zuclopenthixol hydrochloride).
- CLOPIXOL ACUPHASE: zuclopenthixol acetate.
- CLOPIXOL DEPOT: zuclopenthixol decanoate.

Non-medicinal ingredients:

- CLOPIXOL: castor oil (hydrogenated), copovidone, ferric oxide, glycerol, hypromellose, lactose, Macrogol 6000, magnesium stearate, microcrystalline cellulose, potato starch, talc, and titanium dioxide
- CLOPIXOL ACUPHASE: medium-chain triglycerides
- CLOPIXOL DEPOT: medium-chain triglycerides

CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT come in the following dosage forms:

- CLOPIXOL tablets: 10 mg and 25 mg zuclopenthixol (as zuclopenthixol hydrochloride).
- CLOPIXOL ACUPHASE solution for injection: 50 mg/mL zuclopenthixol acetate.
- CLOPIXOL DEPOT solution for injection: 200 mg/mL zuclopenthixol decanoate.

Do not use CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT if:

- you are allergic to:
 - zuclopenthixol or to any of the other ingredients in CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT.
 - thioxanthenes (group of medicines used to treat nervous, mental and emotional conditions).
- you suffer from impaired consciousness (central nervous system depression) due to:
 - the influence of alcohol or drugs such as barbiturates and opioids;
 - brain damage;
 - insufficient blood flow to the tissues of your body as a result of problems with your circulatory system (circulatory collapse);
 - being in a deep state of prolonged unconsciousness (comatose state); or
 - any other causes.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT. Talk about any health conditions or problems you may have, including if you:

- have had an allergic reaction to any medicine that you have taken to treat your condition.
- are taking any other medicines.
- are pregnant, think you might be pregnant or are planning to become pregnant. CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT can cross the placenta barrier and may harm your unborn baby. Therefore, taking these medicines during pregnancy is not recommended unless you and your healthcare professional decide that the potential benefits markedly outweigh the potential risks to your baby.
- are breast-feeding or planning to breast-feed. CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT can pass into your breast milk and harm your baby. Talk to your healthcare professional about the best way to feed your baby if you take CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT.
- drink alcohol or use recreational drugs.
- have liver or kidney problems.
- have Parkinson's disease as CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT may worsen your condition.
- have a history of seizures (fits). CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT may increase your risk of seizure by lowering your seizure threshold.
- are elderly and have dementia.
- have narrow angle glaucoma or pressure inside your eye(s).
- have had a stroke or are at risk for stroke.
- have been told by a healthcare professional that you have low levels of potassium or magnesium in your blood.
- have or have a family history of:
 - heart problems
 - any problems with the way your heart beats
 - heart disease
- have risk factors for developing blood clots such as:
 - a family history of blood clots
 - are over the age of 65
 - are smoking
 - are overweight
 - have had a recent major surgery (such as hip or knee replacement)
 - are not able to move due to air travel or other reasons
 - are taking oral birth control ("The Pill")
- have or have had breast cancer.
- have tumours in your pituitary gland.
- have diabetes or a family history of diabetes as CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT may increase your blood sugar levels.
- know that you have or have had a low white blood cell count in the past.
- are at risk for aspiration pneumonia.
- have one of the following rare hereditary diseases:
 - galactose intolerance

- Lapp lactase deficiency
 - glucose-galactose malabsorption
- CLOPIXOL tablets contain lactose.

Other warnings you should know about:

Tardive dyskinesia (TD): CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT, like other antipsychotic medications, can cause potentially irreversible muscle twitching or unusual/abnormal movement of the face or tongue or other parts of your body.

Hyperprolactinemia (increased levels of prolactin): CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT can raise your levels of a hormone called “prolactin”. This is measured with a blood test. Symptoms may include:

- In men:
 - swelling in the breast
 - difficulty in getting or maintaining an erection or other sexual dysfunction
- In women:
 - discomfort in the breasts
 - leaking of milk from the breasts (even if not pregnant)
 - missing your menstrual period or other problems with your cycle

If you have high levels of prolactin and a condition called hypogonadism you may be at an increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

Effects in newborns: In some cases, babies born to mothers taking CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT during pregnancy have symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may get better on their own. Be prepared to get immediate medical help for your baby if they:

- have trouble breathing
- are overly sleepy
- have muscle stiffness or floppy muscles (like a rag doll)
- are shaking
- are having trouble feeding

Driving and using machines: CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT can cause drowsiness. Before you do tasks which may require special attention, you should wait until you know how you react to CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT.

Check-ups and testing: Your healthcare professional may do check-ups and tests before you start taking CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT and during your treatment. These may include:

- blood tests to monitor your:
 - blood sugar levels.
 - complete blood cell count. This test measures the number and quality of the red blood cells, white blood cells and platelets.
 - prolactin levels (a hormone in your body).
- body weight checks to monitor any weight gain.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

Serious drug interactions:

Serious drug interactions with CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT include:

- Barbiturates, used to treat insomnia, anxiety and seizures
- Opioids, used to relieve pain
- Alcohol. You should not drink alcohol while taking CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT.
- Certain antipsychotic medications (e.g., thioridazine)
- Medicines used to treat an abnormal heart beat (e.g., quinidine, amiodarone, sotalol)
- Certain antibiotics (e.g., erythromycin, moxifloxacin)
- Lithium, used to treat manic episodes in bipolar disorder
- Medicines called “CYP2D6 inhibitors”.

The following may also interact with CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT:

- Other antipsychotic medications.
- Hypnotics (also known as “sleeping pills”), used to treat insomnia
- Medicines used to treat high blood pressure (e.g., adrenergic antagonists).
- Medicines used to treat depression (e.g., tricyclic antidepressants).
- Medicines used to treat Parkinson’s disease (e.g., levodopa) and similar medicines called “dopamine agonists”.
- Medicines that can cause bone marrow suppression (bone marrow unable to produce blood cells) such as therapies/medications used to treat cancer.
- Medicines called “anticholinergics”, which causes constipation or may affect your ability to empty your bladder.
- Metoclopramide, used to relieve nausea and treat the symptoms of slow stomach emptying.
- Medicines known to cause an electrolyte imbalance (e.g., thiazide diuretics, also known as “water pills”)

How to take CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT:

- Take CLOPIXOL tablets or get CLOPIXOL ACUPHASE or CLOPIXOL DEPOT injections exactly as prescribed by your healthcare professional.
- Your healthcare professional will prescribe the lowest effective dose.
- CLOPIXOL tablets may be taken with or without food. Swallow tablets with water. Do **NOT** chew them.
- CLOPIXOL ACUPHASE and CLOPIXOL DEPOT are given by:
 - injection into the muscle (intramuscular) of your buttock.
 - a healthcare professional in a healthcare setting.
- If you stop taking your tablets or coming for your injections, your symptoms may return. **Do not stop your treatment unless told to do so by your healthcare professional.**

- You may feel withdrawal symptoms if you suddenly stop your treatment. These may include: nausea, vomiting, loss of appetite, diarrhea, runny nose, sweating, muscle aches and pain, “pins and needles” sensations, trouble sleeping, or feeling restless, anxious or agitated. You may also experience vertigo, alternate feelings of warmth or coldness, and shaking (tremors). Symptoms may begin within 1 to 4 days of withdrawal and decrease within 7 to 14 days.

Usual dose:

The dose of CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT prescribed to you will depend on your condition. Your healthcare professional may change your dose depending on how you respond to your treatment.

CLOPIXOL tablets:

- For acute treatment: Usual starting dose: 10 mg to 50 mg per day given in divided doses. Your dose may be increased by 10 mg to 20 mg every 2 to 3 days depending on how you respond to CLOPIXOL. Usual dosage range: 20 mg to 60 mg per day.
- For maintenance treatment: Usual dosage range: 20 to 40 mg per day.
- Maximum daily dose: 100 mg.

CLOPIXOL ACUPHASE injection (for acute treatment):

- Usual dosage range: 50 mg to 150 mg. Injection may be repeated every 2 to 3 days if necessary. Some patients may need an additional injection 1 to 2 days after the first injection.
- Maximum cumulative dose: 400 mg.
- Not recommended for treatment longer than 2 weeks.

CLOPIXOL DEPOT injection (for maintenance treatment):

- Usual dosage range: 150 mg to 300 mg every 2 to 4 weeks.

Overdose:

Symptoms of an overdose with CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT may include:

- drowsiness
- state of deep unconsciousness (coma)
- unusual movements
- convulsions
- low blood pressure
- slow, rapid or irregular heartbeat
- insufficient blood flow to the tissues of your body (circulatory shock)
- heart stops beating suddenly (cardiac arrest)
- high or low body temperature

If you think you, or a person you are caring for, have taken too much CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada’s toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

It is important not to miss your scheduled dose.

- **CLOPIXOL** tablets: If you miss a dose, take it as soon as you remember. If it is almost time for your next dose, skip the missed dose and take your next dose as scheduled. Do not take two doses at once to make up for the missed dose.
- **CLOPIXOL ACUPHASE** and **CLOPIXOL DEPOT** injections: If you miss an appointment, contact your healthcare professional **right away** to let them know you missed your injection. Your healthcare professional will advise you when to come next for your scheduled appointment.

Possible side effects from using CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT:

These are not all the possible side effects you may have when taking CLOPIXOL, CLOPIXOL ACUPHASE or CLOPIXOL DEPOT. If you experience any side effects not listed here, tell your healthcare professional.

Side effects with CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT may include:

- Drowsiness, or trouble falling or staying asleep,
- Dizziness, or feeling like you or the room is spinning (vertigo)
- Nausea or vomiting
- Lack of energy
- General feeling of discomfort
- Headache
- Fever
- Hot flashes
- Feeling anxious, agitated or irritable
- Trouble concentrating, or lack of interest or concern
- Abnormal dreams
- Migraine
- Pain at the injection site (for CLOPIXOL ACUPHASE and CLOPIXOL DEPOT)
- Joint pain, or muscle aches or pain
- Back or abdominal pain
- Decreased or increased appetite, changes in body weight
- Dry mouth, increased salivation, indigestion, feeling bloated, diarrhea
- Confusion, memory loss
- Itchy skin, skin rash, skin sensitive to light, skin redness, abnormal pigmentation of the skin, purple coloured spots and patches
- Vision problems, eye inflammation, dilated pupils
- Ringing in the ears, increased sensitivity to sounds
- “pins and needles” sensation on the skin
- Increased sweating
- Shortness of breath
- Sore throat or stuffy nose
- Problems with speech
- Problems with urination
- Abnormal walking pattern
- Feeling faint
- Changes in sex drive, difficulty to achieve orgasm, difficulty to get or keep an erection
- Breast growth in males

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Depression (sad mood that won't go away): difficulty sleeping or sleeping too much, changes in appetite or weight, feelings of worthlessness, guilt, regret, helplessness or hopelessness, withdrawal from social situations, family, gatherings and activities with friends, reduced libido (sex drive) and thoughts of death or suicide. If you have a history of depression, your depression may become worse		✓	
Dystonia: twisting movements that you cannot control and can affect posture or the face including eyes, mouth, tongue or jaw, tightness of the throat, difficulty swallowing or breathing which may lead to choking		✓	
Extrapyramidal symptoms (movement disorder): feeling restless, tense, involuntary muscle contractions, continuous spasms, rigidity, slowness of movement, tremor, jerky movements, abnormal walking pattern		✓	
Hallucinations (seeing or hearing things that are not there)		✓	
Hypertonia (muscle tension): feeling tense, increased muscle tone or stiff muscles		✓	
New or worsening-constipation		✓	
Tachycardia (abnormally fast heartbeat): Sensation of rapid, pounding heart beat, dizziness, shortness of breath		✓	
Uncommon			
Dyskinesia: involuntary movements that you can't control,		✓	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
muscle spasms, or muscle twitching			
Hypotension (low blood pressure): dizziness, fainting, light-headedness, blurred vision, nausea, vomiting, fatigue (may occur when you go from lying or sitting to standing up)		✓	
Oculogyric crisis (neurological disorder): involuntary, often upward, eye muscle spasms			✓
Seizures (fits): loss of consciousness with uncontrollable shaking			✓
Tardive dyskinesia : muscle twitching or abnormal movement of your face or tongue or other parts of your body		✓	
Rare			
Anaphylactic reaction (severe allergic reaction): difficulty swallowing or breathing, wheezing, feeling sick to your stomach and throwing up, hives or rash, swelling of the face, lips, tongue or throat			✓
Diabetic ketoacidosis (DKA) : difficulty breathing, nausea, vomiting, stomach pain, loss of appetite, confusion, thirst, unusual fatigue, sleepiness or tiredness, a sweet or metallic taste in the mouth, sweet smelling breath, or different odour to urine or sweat			✓
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		✓	
Hyperprolactinemia (elevated prolactin levels): irregular menstrual cycles, production and discharge of breast milk, abnormal hair growth, infertility		✓	
Leukopenia (Low white blood cells): infections, fatigue, fever,			✓

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
aches, pains, and flu-like symptoms			
Neuroleptic malignant syndrome (NMS): severe muscle stiffness or inflexibility with high fever, rapid or irregular heartbeat, sweating, state of confusion or reduced consciousness			✓
Priapism: long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
QT prolongation (a heart rhythm condition): irregular heartbeat, dizziness, fainting, seizures			✓
Stroke (bleeding or blood clot in the brain): sudden weakness or numbness of the face, arms, or legs and speech or vision problems			✓
Very rare			
Liver disorder: yellowing of the skin or eyes, dark urine and pale stools, abdominal pain, nausea, vomiting, loss of appetite		✓	
Venous thromboembolism (blood clots): swelling, pain and redness in an arm or leg that is warm to touch. You may develop sudden chest pain, difficulty breathing and heart palpitations			✓
Unknown			
Dysphagia: tightness of the throat, difficulty swallowing which may lead to choking or breathing difficulty			✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

- CLOPIXOL tablets should be stored in a safe place, between 15°C and 25°C. Safely discard any CLOPIXOL tablets you no longer use or that have passed the expiry date on the label. Ask your pharmacist how to properly dispose of them.
- CLOPIXOL ACUPHASE and CLOPIXOL DEPOT will be stored by your healthcare professional between 15°C and 25°C, protected from light.
- Keep out of reach and sight of children.

If you want more information about CLOPIXOL, CLOPIXOL ACUPHASE and CLOPIXOL DEPOT:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); or the manufacturer's website <http://www.lundbeck.ca>, or by calling 1-800-586-2325.
- This information is current up to the time of the last authorization date shown below, but more current information may be available from the manufacturer.

This leaflet was prepared by Lundbeck Canada Inc.

Date of Authorization: 2025-07-18.