

PART III: CONSUMER INFORMATION

^{Pr}Clopixol®

Zuclopendixol Tablets Lundbeck Std.
(10 mg and 25 mg zuclopendixol as zuclopendixol hydrochloride)

^{Pr}Clopixol-Acuphase®

50 mg/mL Zuclopendixol Intramuscular Injection
(45.25 mg/mL zuclopendixol as zuclopendixol acetate)

^{Pr}Clopixol® Depot

200 mg/mL Zuclopendixol Intramuscular Injection
(144.4 mg/mL zuclopendixol as zuclopendixol decanoate)

This leaflet is part III of a three-part "Product Monograph" published when ^{Pr}Clopixol®, ^{Pr}Clopixol-Acuphase® and ^{Pr}Clopixol® Depot were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Clopixol. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information leaflet carefully before you start your medicine, even if you have taken this drug before. Keep this leaflet handy in order to consult while taking your medication.

Clopixol has been prescribed only for you. Do not give it to anybody else.

ABOUT THIS MEDICATION

What the medication is used for:

Clopixol is a prescription medicine that belongs to a family of medicines used to treat schizophrenia.

You may be given Clopixol in the form of tablets or by injection. Depending on the circumstances, your doctor will decide which form of Clopixol is right for you.

Clopixol tablets need to be taken **every day** to be effective.

If you receive Clopixol by injection, it will be administered by a doctor or nurse. There are actually two forms of Clopixol injection, one which is effective when administered every 2-3 days, and another which is effective when administered as infrequently as once every 2-4 weeks.

What it does:

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 that are causing the symptoms of your illness.

When it should not be used:

- If you are allergic to any of its ingredients (see **WHAT THE NON-MEDICINAL INGREDIENTS ARE**)
- If you suffer from impaired consciousness due to the influence of alcohol or drugs such as barbiturates and opiates, or as a result of brain damage, shock (circulatory collapse), or being in a comatose state
- If you suffer from depression

What the medicinal ingredient is:

Each Clopixol® contains Zuclopendixol Tablets Lundbeck Std. (as hydrochloride). Clopixol-Acuphase injection contains zuclopendixol acetate. Clopixol Depot injection contains zuclopendixol decanoate.

What the non-medicinal ingredients are:

Clopixol tablets:

castor oil (hydrogenated), copovidone, ferric oxide, glycerol, hypromellose, lactose, Macrogol 6000, magnesium stearate, microcrystalline cellulose, copovidone, potato starch, talc, titanium dioxide

Clopixol-Acuphase:

medium-chain triglycerides (vegetable oil)

Clopixol-Depot:

medium-chain triglycerides (vegetable oil)

What dosage forms it comes in:

Clopixol is available as a tablet and as an injection.

Tablets: ^{Pr}Clopixol® tablets are available in two strengths. The 10 mg tablet is light-red brown and the 25 mg tablet is red-brown.

Injection: There are two forms of Clopixol for intramuscular injection. ^{Pr}Clopixol-Acuphase® is a 50 mg/mL solution (45.25 mg/mL zuclopendixol as zuclopendixol acetate) and ^{Pr}Clopixol® Depot is a 200 mg/mL solution (144.4 mg/mL zuclopendixol as zuclopendixol decanoate).

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Neuroleptic malignant syndrome (NMS) is a rare, but life-threatening, disorder of the nervous system that has been linked with drugs such as Clopixol. It is characterized by high fever, unusual stiffness of the muscles and disorder of your consciousness, sweating and fast heart rate.

BEFORE you use Clopixol talk to your doctor or pharmacist if:

- you have used Clopixol or any other treatment for schizophrenia before and if you had any problems
- you are taking any other prescription or non-prescription medicines
- you are pregnant or thinking of becoming pregnant, or if you are breast-feeding

- you regularly drink a lot of alcohol
- you have any liver problems, Parkinson's disease or have ever had seizures
- you have dementia
- you have glaucoma
- you have any kidney problems
- you have risk factors for stroke (e.g. smoking, high blood pressure).
- you have hypokalemia or hypomagnesia (too little potassium or magnesium in your blood)
- you have a history of cardiovascular disorders
- you or someone in your family has a history of blood clots
- you are being treated for cancer (applies to Clopixol Depot only)
- you use any other antipsychotic medicine
- you are allergic to any of its ingredients (see ABOUT THIS MEDICATION, What The Medicinal Ingredient Is, What the Non-medicinal Ingredients Are)

It is important that you tell your doctor about all your past and present medical conditions.

Effects on Newborns:

In some cases, babies born to a mother taking Clopixol during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

Effects on Fertility:

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

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Clopixol include:

- tricyclic antidepressant medicines
- guanethidine and similar medicines (used to lower the blood pressure)
- barbiturates and similar medicines
- levodopa and similar medicines (used to treat Parkinson's disease)
- metoclopramide (used in the treatment of gastro-intestinal disorders)
- other antipsychotic medicines (e.g. thioridazine)
- medicines that change the heartbeat (e.g. quinidine, amiodarone, sotalol, erythromycin, moxifloxacin, lithium)

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

Consult your doctor before taking other medications, including

over-the-counter medicines and herbal remedies. Some drugs can produce additional side-effects when they are used in combination with Clopixol.

PROPER USE OF THIS MEDICATION

Usual dose:

Clopixol Tablets: It is very important that you take Clopixol exactly as your doctor instructs you. Never increase or decrease the amount of Clopixol you are taking unless your doctor tells you to. Clopixol may be taken with or without food.

Discontinued dose:

Abrupt discontinuation of Clopixol Tablets may be accompanied by withdrawal symptoms. The most common symptoms are nausea, vomiting, anorexia, diarrhoea, rhinorrhoea, sweating, myalgias, paraesthesias, insomnia, restlessness, anxiety, and agitation. You may also experience vertigo, alternate feelings of warmth and coldness, and tremor. Symptoms generally begin within 1 to 4 days of withdrawal and decrease within 7 to 14 days.

Clopixol Injection: If you are prescribed Clopixol by intramuscular injection, it will be given by a doctor or nurse. It is very important to keep your scheduled appointments for the injections.

Overdose:

Contact your doctor or nearest hospital emergency department as soon as you realize you have taken too much Clopixol, even if you do not feel sick. Symptoms of overdose may include:

- somnolence
- coma
- unusual movements
- convulsions
- shock
- 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.

Missed dose:

Clopixol Tablets: If you miss a dose, take it as soon as you remember, as long as it is more than 6 hours before the next dose is due. If it is less than 6 hours before the next dose is due, just take your next regularly scheduled dose and try not to miss any more. Do not try to make up for a missed dose by doubling up on the next dose.

Clopixol Injection: If you miss an appointment, contact your doctor as soon as possible in order to schedule a new appointment.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

At the beginning of treatment, Clopixol may make you feel

drowsy and dizzy so you should not drive a car or use any tools or machines until you are sure Clopixol does not affect your mental alertness.

Side-effects that have been reported by patients taking Clopixol include: muscle spasm, stiffness, shaking or uncontrolled body movements. These can happen in different parts of the body, such as the tongue, face, mouth, jaw, eyes, hands, arms and legs. Contact your doctor if this happens to you.

Other possible side-effects include dry mouth, dizziness, blurred or altered vision (difficulty reading small print), constipation, excessive salivation or sweating, trouble passing urine. Decreases in blood pressure, increases in heart rate, weight changes, skin rash, decreased sexual interest or function, and changes in your monthly cycle (if you are female).

In addition, 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.

Your doctor should check your body weight before starting Clopixol and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting Clopixol. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

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

Tell your doctor or pharmacist if you think you have any of these or other effects while taking Clopixol.

Any fever (increased temperature) or soreness of the mouth, gums, or throat that happens while you are taking Clopixol should be reported to your doctor **immediately**.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency assistance
		Only if severe	In all cases	
Common	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)	✓		
Uncommon	Unusual movements of the mouth and tongue		✓	
	Yellowing of the skin and the white in the eyes and extremities.		✓	
	High fever, unusual stiffness of the muscles and disorder of your consciousness, especially if occurring with sweating and fast heart rate			✓
	Circular movement of the eye (oculogyration)		✓	
	Convulsion			✓

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Uncommon	Rash, skin reaction due to sensitivity to light (photosensitivity reaction)		✓	
	Bleeding underneath the skin seen by red or purple discolorations on the skin (purpura)		✓	
	Severe allergic reaction (symptoms include skin rash, hives, swelling, difficulty breathing)			✓
	Long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
	New or worsening constipation		✓	

This is not a complete list of side effects. For any unexpected effects while taking Clopixol, contact your doctor or pharmacist.

HOW TO STORE IT

Clopixol Tablets should be kept in a safe place, between 15°C and 25°C.

Clopixol-Acuphase and Clopixol Depot are single-use ampoules that should be kept in a safe place, between 15°C and 25°C, protected from light.

Keep Clopixol out of the reach and sight of children.

Safely discard any Clopixol that has passed the expiry date on the label.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at: www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:

- Fax toll-free to 1-866-678-6789, or
- Mail to:

Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions or concerns and to find the full product monograph prepared for healthcare professionals, go to <http://www.lundbeck.ca> or contact the sponsor, Lundbeck Canada Inc. at 1-800-586-2325.

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