

# Clopixol Acutard

## Notice: Information for the user

### Clopixol Acutard 50 mg/ml injectable solution Zuclopenthixol acetate

Please read this leaflet carefully before using 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, pharmacist or nurse.
- This medication has been prescribed specifically for you. Do not give it to anyone else. It could be harmful to them, even if their symptoms are the same as yours.
- If you experience any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

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## 1. WHAT IS CLOPIXOL ACUTARD AND WHAT IS IT USED FOR?

Clopixol Acutard contains the active ingredient zuclopenthixol. Clopixol Acutard belongs to a group of medicines called antipsychotics (also known as neuroleptics).

These medicines act on the nerve pathways in specific parts of the brain and help to restore certain chemical imbalances in the brain that cause your illness.

Clopixol Acutard is used for the treatment of acute forms of mental disorders (acute psychoses), which require rapid action and a duration of action of 2 to 3 days.

However, your doctor may prescribe Clopixol Acutard for another reason. If you have any questions about how to use Clopixol Acutard for you, please consult your doctor.

## 2. WHAT INFORMATION SHOULD YOU KNOW BEFORE USING CLOPIXOL ACUTARD?

### Never use Clopixol Acutard

- if you are allergic to the active substance or to any of the other ingredients of this medicine listed in section 6.

- if you are in a state of diminished consciousness.

### **Warnings and precautions**

: Talk to your doctor, pharmacist or nurse before using Clopixol Acutard.

- If you suffer from liver or kidney disease.
- If you have a history of epileptic seizures or convulsions.
- If you are diabetic, your doctor may adjust your antidiabetic therapy.
- If you suffer from brain damage (which can be caused by alcohol or organic solvent intoxication).
- If you have risk factors for a stroke (e.g. smoking, high blood pressure).
- If you suffer from hypokalemia or hypomagnesemia (too little potassium or magnesium in your blood) or if you show a genetic predisposition for either of the two.
- If you have a history of heart or blood vessel disease.
- If you are taking other antipsychotic medications (for mental illnesses).
- If you suffer from glaucoma.
- If you have an enlarged prostate.
- If you have breast cancer or have had breast cancer treatment.
- If you, or someone in your family, has a history of blood clots, given that blood clot formation has previously been associated with medications of this type.

Movement disturbances such as tremors and muscle spasms may occur, particularly during the first few days of treatment. Inform your doctor, as a dose reduction may be necessary. Inform your doctor if you experience a persistent and constant urge to move, as these symptoms can be controlled with appropriate treatment. Inform your doctor if you experience uncontrolled facial and jaw movements, as treatment may need to be stopped.

Difficulty swallowing may occur as a side effect of extrapyramidal symptoms (such as tremors, muscle spasms or movement disorders), sedation (drowsiness), increased salivation and/or neuroleptic malignant syndrome (a rare and serious reaction with fever, muscle rigidity, changes in blood pressure and coma).

### **Children and adolescents:**

Clopixol Acutard is not recommended for this patient group.

### **Other medicines and Clopixol Acutard:**

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines.

If you are using any of the following medicines, please tell your doctor:

- Tricyclic antidepressants
- Lithium (used to prevent and treat bipolar disorder). The combination may be harmful to the brain.
- Guanfacine and similar medications (used to lower blood pressure)
- Barbiturates and similar drugs (drugs that cause drowsiness)
- Epilepsy medications
- Medications that can cause seizures (e.g., those containing tramadol)
- Levodopa and similar products (used to treat Parkinson's disease)
- Metoclopramide (used to treat gastrointestinal disorders)
- Piperazine (used to treat infections caused by roundworms)
- Medications that disrupt the body's water and salt balance (too little potassium or magnesium in the blood)
- Medications that may increase the amount of Clopixol Acutard in your blood.

The following medications cannot be used at the same time as Clopixol Acutard:

- Medications that can alter heart rhythm (e.g. quinidine, amiodarone, sotalol, dofetilide, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium).
- Other antipsychotic drugs (for mental illnesses) (e.g., thioridazine).

### **Clopixol Acutard with alcohol:**

Clopixol Acutard can intensify the sedative effects of alcohol and make you drowsy. For this reason, it is advisable not to drink alcohol while taking Clopixol Acutard.

### **Pregnancy, breastfeeding and fertility:**

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

#### **Pregnancy:**

If you are pregnant or think you may be pregnant, talk to your doctor. Clopixol Acutard should not be used during pregnancy unless strictly necessary.

The following symptoms may occur in newborns of mothers who used Clopixol Acutard during the last trimester (the last three months of their pregnancy): tremors, muscle stiffness and/or weakness, drowsiness, agitation, breathing problems, and feeding difficulties. If your baby experiences any of these symptoms, it is advisable to contact your doctor.

#### **Breastfeeding:**

If you are breastfeeding, ask your doctor for advice. Clopixol Acutard should not be used while breastfeeding, as it is found in small amounts in breast milk.

#### **Fertility:**

Animal studies have shown that Clopixol may affect fertility. Consult your doctor.

**Driving and operating machinery:**

When using Clopixol Acutard, there is a risk of drowsiness or dizziness, especially at the beginning of treatment. If this occurs, do not drive or operate machinery until these symptoms have disappeared.

### 3. HOW TO USE CLOPIXOL ACUTARD?

A small volume of Clopixol Acutard is drawn into a syringe and injected into the gluteal muscle. Your doctor will determine the amount of medication to administer and the timing of the injection.

The recommended dose is:

**Adults**

: Generally, you will receive a 1 ml–3 ml (50 mg–150 mg) injection every 2–3 days. You may need another injection 1–2 days after the first injection . If you need more than 2 ml, the injection will likely be given in two different locations.

**Elderly patients (over 65 years of age)**

generally receive lower doses. Maximum 100 mg per injection.

**Patients at specific risk:**

Patients with liver problems normally receive lower doses.

**Use in children:**

The use of Clopixol Acutard is not recommended in children.

If you feel that Clopixol Acutard has too strong or too weak an effect for you, talk to your doctor.

**Duration of treatment:**

This medicine is not suitable for long-term use. The duration of treatment should not exceed 2 weeks, and during this period, no more than 4 injections or 8 ml (400 mg) should be administered in total.

If you require further treatment after the Clopixol Acutard injections, your doctor will prescribe appropriate medication.

It is very important to follow your doctor's prescribed treatment exactly.

**If you have used more Clopixol Acutard than you should have, remember**

that Clopixol Acutard is administered by a doctor or nurse; therefore, it is unlikely that you will use more Clopixol Acutard than you should. However, if in the unlikely event that you have used too much Clopixol Acutard, or if you discover that someone else has taken too much Clopixol Acutard, contact your doctor, pharmacist, the Poison Control Center (070 245 245), or the nearest hospital emergency department immediately, even if you do not feel unwell or show any signs of poisoning. Take your Clopixol Acutard pack with you if you go to the doctor or hospital.

Signs that might indicate Clopixol Acutard has been taken in too high a dose could include:

- drowsiness
- loss of consciousness (coma)
- unusual movements
- convulsions
- shock
- high or low body temperature
- changes in heart rhythm, including irregular or slower heart rhythms, when Clopixol Acutard has been used in overdose with other drugs that affect heart function.

**If you stop using Clopixol Acutard,**

your doctor will decide when it is appropriate to stop treatment. They will likely reduce the dose gradually to protect you from unpleasant symptoms that occur if treatment is stopped abruptly (e.g., sleep problems, muscle stiffness, malaise).

If you have any further questions about the use of this medicine, ask your doctor, pharmacist or nurse for more information.

### 4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, Clopixol Acutard can cause side effects, although not everyone gets them.

**If you experience any of the symptoms listed below, you should consult your doctor immediately or go to the hospital immediately.**

Uncommon (affects less than 1 in 100 people)

- Unusual movements of the mouth and tongue. These can be an early sign of a condition called tardive dyskinesia.

Rare (affects fewer than 1 in 1,000 people)

- Difficulty swallowing (see section 2)

Very rare (affecting fewer than 1 in 10,000 people)

- High fever, unusual muscle rigidity with altered consciousness, especially if accompanied by sweating and a rapid heartbeat. These symptoms could be signs of a rare condition called neuroleptic malignant syndrome. This has been reported after the use of various antipsychotics.
- Yellowing of the skin and whites of the eyes. May indicate a liver disorder and may be a sign of jaundice.
- Blood clots in the veins, particularly in the legs (symptoms include swelling, pain, and redness in the legs), can travel through the blood vessels to the lungs, causing chest pain and difficulty breathing. If you experience any of these symptoms, seek immediate medical attention.

**The following side effects are most pronounced at the beginning of treatment and disappear in most cases when treatment continues.**

Very common (affecting more than 1 in 10 people)

- Drowsiness, difficulty staying still or immobile (akathisia), involuntary movements (hyperkinesia), slow or decreased movements (hypokinesia)
- Dry mouth
- Movement disorder (extrapyramidal symptoms) – due to effects on a part of the brain that regulates movement, which may lead to tremors, muscle spasms or movement disorders (see section 2)

Frequent (affects less than 1 in 10 people)

- Rapid heart rate (tachycardia), sensation of a fast, strong or irregular heartbeat (palpitations)
- Tremors, twisting or repetitive movements or abnormal posture due to muscle contractions (dystonia), increased muscle rigidity (hypertonia), dizziness, headaches, tingling, prickling or numbness of the skin (paresthesia), attention deficit, memory loss (amnesia), gait disturbances.
- Low blood pressure (hypotension), orthostatic hypotension (dizziness upon standing up)
- Difficulty seeing objects clearly that are very close to the eye (accommodation disorder), abnormal vision
- A sensation of spinning or swaying when you are not moving (vertigo)
- Blocked nose (nasal congestion), difficulty or painful breathing (dyspnea)
- Increased salivation (salivary hypersecretion), constipation, vomiting, digestive problems or discomfort in the upper abdomen (dyspepsia), diarrhea
- Problems urinating (micturition disorders), inability to urinate (urinary retention), frequent urination (polyuria)
- Excessive sweating (hyperhidrosis), itching (pruritus)
- Muscle pain (myalgia)
- Increased appetite, weight gain
- Fatigue, weakness (asthenia), feeling unwell, pain
- Insomnia, depression, anxiety, nervousness, abnormal dreams, arousal, decreased sexual desire (decreased libido)

Uncommon (affects less than 1 in 100 people)

- Exaggerated reflexes or a stronger than normal reaction to stimuli (hyperreflexia), spastic movements (dyskinesia), parkinsonism, fainting (syncope), inability to coordinate movements (ataxia), speech disorders, decreased muscle tone (hypotonia), seizures, migraine.
- Rotating eye movements (oculogyric crisis), dilation of the pupil (mydriasis).
- Hypersensitivity to certain tones (frequencies) or difficulty tolerating everyday sounds (hyperacusis), ringing in the ears (tinnitus)
- Abdominal pain, nausea, flatulence
- Skin rash, skin reaction due to sensitivity to light (photosensitivity reaction), pigmentation disorders, shiny and yellowish skin due to increased secretion of sebaceous matter (sebum) (seborrhea), eczema or inflammation of the skin (dermatitis), red or blue discoloration of the skin due to subcutaneous bleeding (purpura), skin reaction at the injection site.
- Muscle stiffness, inability to open the mouth (trismus), neck twisting with abnormal head tilt (torticollis - neck stiffness)
- Decreased appetite, weight loss
- Hot flashes
- Thirst, abnormally low body temperature (hypothermia), fever (pyrexia)
- Red or irritated skin at the site of the Clopixol Acutard injection.
- Abnormal liver function tests
- Sexual problems [ delayed ejaculation, erectile dysfunction, female orgasmic disorders, vaginal dryness (vulvovaginal dryness) ]
- Exaggerated indifference to the presence of others (apathy), nightmares, increased sexual desire (increased libido), confusion.

Rare (affects fewer than 1 in 1,000 people)

- Decreased number of blood platelets (thrombocytopenia), decreased number of white blood cells (neutropenia), decreased number of white blood cells (bone marrow poisoning) (leukopenia), bone marrow poisoning (agranulocytosis)
- High levels of the hormone prolactin in the blood (hyperprolactinemia)
- High blood sugar levels (hyperglycemia), impaired glucose tolerance (glucose intolerance), high levels of fats (lipids) in the blood (hyperlipidemia).
- Allergic reaction (hypersensitivity), acute systemic reaction, and severe allergic reaction (anaphylactic shock)
- Breast development in men (gynecomastia), excessive milk secretion (galactorrhea), absence of menstrual cycle (amenorrhea), painful and prolonged erection of the penis in the absence of sexual desire or arousal (priapism).

As with other medications that work in the same way as Clopixol Acutard, rare cases of the following side effects have been reported:

- QT prolongation (slowed heart rate and changes in the electrocardiogram (ECG))

- Irregular heartbeats (ventricular arrhythmias, ventricular fibrillation, ventricular tachycardia)
- Torsades de Pointes (a particular form of irregular heartbeat)
- In a few rare cases, irregular heartbeats (arrhythmias) have reportedly resulted in sudden death.

In elderly people with dementia, a slight increase in the number of deaths has been reported in patients taking antipsychotics compared to those not receiving them.

**Reporting of side effects:**

If you experience 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 national reporting systems:

**In Belgium:**

Federal Agency for Medicines and Health Products

[www.afmps.be](http://www.afmps.be)

Vigilance Division:

Website: [www.notifierunefetindesirable.be](http://www.notifierunefetindesirable.be)

Email: [adr@fagg-afmps.be](mailto:adr@fagg-afmps.be)

**In Luxembourg:**

Regional Pharmacovigilance Centre of Nancy or Pharmacy and Medicines Division of the Directorate of Health.

Website: [www.guichet.lu/pharmacovigilance](http://www.guichet.lu/pharmacovigilance)

By reporting side effects, you help provide more information on the safety of the medicine.

## 5. HOW TO STORE CLOPIXOL ACUTARD

In general, it is your doctor or nurse who will keep Clopixol Acutard for you.

Keep out of the sight and reach of children.

Store the bulbs in the outer packaging, away from light.

Do not use this medicine after the expiry date shown on the carton and label after "EXP". The expiry date refers to the last day of that month.

Do not dispose of any medication down the drain or in household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.

## 6. PACKAGE CONTENTS AND OTHER INFORMATION

### **What Clopixol Acutard contains:**

The active ingredient is zuclopenthixol acetate.

Each ml of Clopixol Acutard contains 50 mg of zuclopenthixol acetate.

The other component is fine vegetable oil (medium chain saturated triglycerides).

### **Appearance of Clopixol Acutard and contents of outer packaging**

Clopixol Acutard 50 mg/ml injectable solution is available in 1 ml (50 mg) glass ampoules in a cardboard box.

Clopixol Acutard is a clear, light yellow liquid.

Clopixol Acutard is available in the following packaging:

Injectable solution 50 mg/1 ml, box of 1 ampoule or 5 ampoules.

Not all presentations may be commercially available.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing Authorisation Holder:*

Lundbeck sa - Stephanie Square Centre - Avenue Louise 65/11 - 1050 Brussels

#### *Manufacturer:*

H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark.

### **Marketing authorization number**

BE140987

LU: 2005088296

### **Method of delivery:**

By medical prescription

**The last date on which this leaflet was approved is 01/2026.**