

Package leaflet: Information for the patient

**Clopixol-Acuphase® 50 mg/ml solution for injection
zuclopenthixol acetate**

Read all of this leaflet carefully before you start 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
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Clopixol-Acuphase is and what it is used for**
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1. What Clopixol-Acuphase is and what it is used for

The name of your medicine is Clopixol-Acuphase 50 mg/ml solution for injection (called Clopixol-Acuphase in this leaflet). Clopixol-Acuphase contains the active substance zuclopenthixol. Clopixol-Acuphase 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 in the brain that are causing the symptoms of your illness.

Clopixol-Acuphase is used for the initial treatment of short-term psychoses including mania or increases in the severity of existing psychoses.

2. What you need to know before Clopixol-Acuphase is given

Clopixol-Acuphase is not given

- If you are allergic (hypersensitive) to zuclopenthixol, other thioxanthene drugs or antipsychotic drugs or any of the other ingredients of this medicine (listed in section 6). Tell your doctor if you think you might be
- If you are feeling less alert than usual, or are drowsy or sleepy or have serious problems with your blood circulation

Warnings and precautions

Talk to your doctor, pharmacist or nurse before Clopixol-Acuphase is given to you:

- If you have a heart condition, including an irregular heart beat (such as a slower heart beat); have had a recent heart attack or have problems that cause ankle swelling or shortness of breath
- If you have liver, kidney or thyroid problems
- If you suffer from epilepsy, or have been told that you are at risk of having fits (for example because of a brain injury or because of alcohol withdrawal)
- If you suffer from Parkinson's disease, or myasthenia gravis (a condition causing severe muscular weakness)
- If you have risk factors for stroke (e.g. smoking, hypertension)
- If you have too little potassium or magnesium in your blood or a family history of irregular heart beats
- If you use other antipsychotic medicines
- If you suffer from diabetes
- 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

Children and adolescents

Clopixol-Acuphase is not recommended in these patients

Other medicines and Clopixol-Acuphase

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

The following medicines should not be taken at the same time as Clopixol-Acuphase:

- Medicines that change the heart beat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines

Tell your doctor or pharmacist if you are taking any of the following medicines

- Tricyclic antidepressants
- Barbiturates or other medicines that make you feel drowsy
- Anticoagulant drugs used to prevent blood clots (e.g. warfarin)
- Anticholinergic drugs (contained in some cold, allergy or travel sickness remedies as well as other medicines)
- Metoclopramide (used to treat nausea and other stomach conditions)
- Piperazine (used to treat worm infections)
- Levodopa or other medicines used to treat Parkinson's disease
- Sibutramine (used to reduce appetite)
- Digoxin (to control heart rhythm)
- Corticosteroids (e.g. prednisolone)
- Medicines used to lower the blood pressure such as hydralazine, alpha blockers (e.g. doxazosin) beta-blockers, methyldopa, clonidine or guanethidine
- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of zuclopenthixol in your blood
- Medicines used to treat epilepsy
- Medicines used to treat diabetes

Clopixol-Acuphase can reduce the effect of adrenaline (epinephrine) and similar drugs.

Tell your doctor, dentist, surgeon or anaesthetist before any operation as Clopixol-Acuphase can increase the effects of general anaesthetics, muscle relaxing drugs and drugs used to prevent clots.

Clopixol-Acuphase with alcohol

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

Pregnancy, breast-feeding and fertility

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

Pregnancy

If you are pregnant or think you might be pregnant, tell your doctor. Clopixol-Acuphase should not be used during pregnancy unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Clopixol-Acuphase in the last trimester (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 may need to contact your doctor.

Breast-feeding

If you are breast-feeding, ask your doctor for advice. Clopixol-Acuphase should not be used when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility

Zuclopenthixol may decrease your sexual activity and fertility. These are not lasting effects. Please talk to your doctor about any problems.

Driving and using machines

There is a risk of feeling drowsy or dizzy, or suffering from blurred vision when being treated with Clopixol-Acuphase, especially at the start of your treatment. If this happens do not drive or use any tools or machines.

3. How Clopixol-Acuphase is given

A small amount of Clopixol-Acuphase is drawn up into a syringe and then injected into the muscle of your buttock or thigh.

Your doctor will decide on the correct amount of medicine to give.

Adults

The usual dose lies between 50-150 mg (1-3 ml) repeated if necessary after 2-3 days. Some patients may require an additional dose 1 or 2 days after the first injection.

Treatment can continue for up to 2 weeks. In this time you may receive a total of 4 injections up to a total dose of 400 mg (8 ml).

If further treatment is necessary, your doctor will prescribe suitable medication immediately or shortly after the Clopixol-Acuphase injections are stopped.

Older patients (above 65 years of age)

Older patients may need smaller doses. The maximum dose per injection is 100 mg.

Patients with special risks

If you have renal failure, your dosage should be reduced to half the usual dosage range. If you have liver problems, the level of zuclopenthixol in your blood may be checked. Patients with liver complaints normally receive doses at half the usual dosage range.

Use in children

Clopixol-Acuphase is not recommended for children.

Duration of treatment

Treatment with Clopixol-Acuphase can continue for up to 2 weeks. After this time if treatment is still needed it can be continued with Clopixol tablets, Clopixol injection or Clopixol Conc. injection.

If you feel that the effect of Clopixol-Acuphase is too strong or weak, talk to your doctor or pharmacist.

If you are given too much Clopixol-Acuphase

Your medicine will be given by your doctor/nurse.

In the unlikely event that you receive too much Clopixol-Acuphase you may experience some symptoms.

Symptoms of overdose may include:

- Drowsiness
- Unconsciousness
- Muscle movements or stiffness
- Fits
- Low blood pressure, weak pulse, fast heart rate, pale skin, restlessness
- High or low body temperature
- Changes in heart beat including irregular heart beat or slow heart rate

You will receive treatment for any of these symptoms from your doctor or nurse.

4. Possible side effects

Like all medicines, Clopixol-Acuphase can cause side effects, although not everybody gets them.

Serious side effects

Stop using Clopixol and seek medical advice immediately if you have any of the following allergic reactions:

- Difficulty in breathing

- Swelling of the face, lips, tongue or throat which causes difficulty in swallowing or breathing
- Severe itching of the skin (with raised lumps)

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.

If you get any of the following symptoms you should **contact your doctor immediately** as your dose may need to be reduced or stopped:

- High fever, unusual stiffness of the muscles and changes in consciousness, especially if occurring with sweating and fast heart rate. These symptoms may be signs of a rare but serious condition called neuroleptic malignant syndrome that has been reported with the use of Clopixol and similar medicines
- Unusual movements of the mouth and tongue as these may be early signs of a condition known as tardive dyskinesia
- Unusual muscle movements (such as circular movements of the eyes), stiffness, tremor and restlessness (for example difficulty in sitting or standing still) as these may be signs of a so-called “extra-pyramidal” reaction
- Any yellowing of the skin and the white of the eyes (jaundice); your liver may be affected

Other side effects:

Side effects are most pronounced the day after the first treatment and usually wear off soon afterwards.

- Throbbing or fast heart beats
- Reduction in blood platelets (which increases the risk of bleeding or bruising) and other blood cell changes
- Drowsiness
- Loss of co-ordination or altered muscle movements (including unusual movements of the mouth, tongue and eyeballs)
- Tremor
- Stiff or floppy muscles (including stiff jaw and neck muscles)
- Dizziness or vertigo
- Headache or migraine
- Numbness or tingling in the arms and legs
- Poor concentration, loss of memory or confusion
- A changed walking pattern
- Abnormal reflexes
- Rigidity of the whole body
- Fainting
- Speech problems
- Fits
- Enlarged pupils or blurred, abnormal vision
- Sensitive hearing or ringing in the ears (tinnitus)
- Stuffy nose
- Shortness of breath

- Dry mouth or increase in saliva
- Feeling sick or vomiting
- Indigestion or stomach pain
- Flatulence (wind), constipation or diarrhoea
- Abnormal urination (increases or decreases in the frequency or amount)
- Increased sweating or greasy skin
- Itching, rashes or skin reactions (including sensitivity to sunlight)
- Skin reactions at injection site
- Changes in skin colour
- Bruising under the skin
- Muscle pain
- Raised blood levels of glucose, lipids or the hormone prolactin
- Loss of control of blood sugar levels
- Changes in appetite or weight
- Low blood pressure
- Hot flushes
- General weakness or pain, tiredness or feeling unwell
- Increased thirst
- Reduced or increased body temperature (including fever)
- Abnormal liver function tests
- Liver enlargement
- Unexpected excretion of breast milk
- Insomnia, abnormal dreams or nightmares
- Depression or anxiety
- Nervousness or agitation
- Lack of emotion or indifference to your surroundings (apathy)
- Changes to your sex drive
- Men may experience breast enlargement or problems with ejaculation or erections (including prolonged erections)
- Women may experience an absence of menstrual periods, vaginal dryness or problems with orgasms

As with other medicines that work in a way similar to zuclopenthixol (the active ingredient of Clopixol), rare cases of the following side effects have been reported:

- Slow heart beat and abnormal ECG heart tracing
- Life threatening irregular heart beats

In rare cases irregular heart beats (arrhythmias) may have resulted in sudden death.

In older people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Reporting of side effects

If you get 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 (see details below)

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

United Kingdom

Via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

Malta

ADR Reporting

The Medicines Authority

Post-Licensing Directorate

Sir Temi Zammit Buildings Malta Life Sciences Park

San Gwann SGN 300

Website: www.medicinesauthority.gov.mt

e-mail: postlicensing.medicinesauthority@gov.mt

5. How to store Clopixol-Acuphase

Your doctor or nurse will store the medicine for you. If you keep it at home:

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date that is printed on the label and carton after EXP. The expiry date refers to the last day of that month.
- Keep the ampoules in the outer carton in order to protect from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Clopixol-Acuphase contains

The active substance is zuclopenthixol acetate.

Each millilitre (ml) of Clopixol-Acuphase contains 50 mg zuclopenthixol acetate.

The other ingredient is thin vegetable oil (purified from coconut oil).

What Clopixol-Acuphase looks like and contents of the pack

Clopixol-Acuphase is an oily liquid.

Clopixol-Acuphase is available in glass ampoules containing 1 ml (50 mg) or 2 ml (100 mg) in cartons of 5 ampoules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

For any information about this medicine, please contact the Marketing Authorisation holder:

Lundbeck Limited

Building K1

2nd floor

Building 3, Abbey View

Everard Close

St Albans

AL1 2PS
UK

Manufacturer
H. Lundbeck A/S
Ottliavej 9
DK-2500 Valby
Denmark

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To request a copy of this leaflet in braille, large print or audio please call free of charge:

0800 198 5000

Please be ready to give the following information:

Product name	Product code number
ClopiXol-Acuphase	PL 0458/0063

This is a service provided by the Royal National Institute of Blind People.

The following information is intended for healthcare professionals only:

ClopiXol-Acuphase 50 mg/ml solution for injection

Administration information for the healthcare professional

Consult the Summary of Product Characteristics for full information on this product

ClopiXol-Acuphase 50 mg/ml solution for injection is a clear, yellowish oil, practically free from particles. It should be administered by deep intramuscular injection into the upper outer buttock or lateral thigh.

Note: As with all oil based injections it is important to ensure, by aspiration before injection, that inadvertent intravascular entry does not occur.

Injection volumes of greater than 2 ml should be distributed between two injection sites.

This product may be mixed in the same syringe with other products in the ClopiXol Injection range.

It should not be mixed with any other injection fluids.