

Package leaflet: Information for the patient

**Depixol® 20 mg/ml solution for injection
flupentixol decanoate**

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
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- 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 Depixol Injection is and what it is used for**
- 2. What you need to know before Depixol Injection is given**
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1. What Depixol Injection is and what it is used for

The name of your medicine is Depixol 20 mg/ml solution for injection (called Depixol Injection in this leaflet).

Depixol Injection contains the active substance flupentixol decanoate. Depixol Injection 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.

Depixol Injection is used for the treatment of schizophrenia and other psychoses.

Your doctor, however, may prescribe Depixol Injection for another purpose. Ask your doctor if you have any questions about why Depixol Injection has been prescribed for you.

2. What you need to know before Depixol Injection is given

Depixol Injection is not given if you

- are allergic (hypersensitive) to flupentixol, other thioxanthene drugs or antipsychotic drugs or any of the other ingredients of this medicine (listed in section 6)
- are feeling less alert than usual or are drowsy or sleepy, or have serious problems with your blood circulation
- are excited or agitated

Warnings and precautions

Talk to your doctor, pharmacist or nurse before Depixol Injection is given 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
- have severe breathing problems (such as asthma or bronchitis)
- have liver, kidney or thyroid problems
- 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)
- suffer from Parkinson's disease, or myasthenia gravis (a condition causing severe muscular weakness)
- have an enlarged prostate or suffer from a condition known as phaeochromocytoma (a rare type of cancer of a gland near the kidney)
- suffer from glaucoma (raised pressure within the eye)
- have risk factors for stroke (e.g. smoking, hypertension)
- have too little potassium or magnesium in your blood or a family history of irregular heart beats
- use other antipsychotic medicines
- suffer from diabetes
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- are treated for cancer

Children and adolescents

Depixol Injection is not recommended in these patients.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Other medicines and Depixol Injection

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 Depixol Injection:

- Medicines that change the heartbeat (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 anti-depressants
- 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) betablockers, methyl dopa, 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 flupentixol in your blood
- Medicines used to treat epilepsy
- Medicines used to treat diabetes

Depixol Injection can reduce the effect of adrenaline (epinephrine) and similar drugs.

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

Depixol Injection with alcohol

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

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might 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 might be pregnant, tell your doctor. Depixol Injection should not be used during pregnancy unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Depixol Injection 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.

Depixol Injection should not be used when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility

Flupentixol 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 and dizzy when being treated with Depixol Injection, especially at the start of your treatment. If this happens do not drive or use any tools or machines until you know you are not affected in this way.

Do not drive if you have blurred vision.

3. How Depixol Injection is given

A small amount of Depixol Injection 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, and how often to give it. The medicine is slowly released from the injection site so that a fairly constant amount of medicine gets into your blood during the period between each dose.

Adults

The usual dose lies between 50 mg every 4 weeks to 300 mg every 2 weeks but some patients require 400 mg every week. The maximum single dose at any one time is 400 mg. If you need more than 2 ml of medicine it will probably be divided between 2 injection sites.

If you haven't received an injection like Depixol Injection before, a small dose of 20 mg is usually given one week before your normal dose to test how well you tolerate the medicine.

If you have been treated with Depixol tablets and you are being transferred to Depixol Injection you may be asked to continue taking the tablets for several days after the first injection.

Your doctor may decide to adjust the amount given, or the interval between injections, from time to time.

If you have liver problems, the level of flupentixol in your blood may be checked.

Older patients (above 65 years)

Starting doses for older or frail patients are usually reduced to a quarter or a half of the dosage range.

Use in children

Depixol Injection is not recommended for children.

Duration of treatment

It may take between four and six months before you feel better. Your doctor will decide the duration of treatment.

If you feel that the effect of Depixol Injection is too strong or weak, talk to your doctor.

It is important that you continue to receive your medicine at regular intervals even if you are feeling completely well, because the underlying illness may persist for a long time. If you stop your treatment too soon your symptoms may return.

If you get more Depixol Injection than you should

Your medicine will be given by your doctor or nurse.

In the unlikely event that you receive too much Depixol Injection 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, Depixol Injection can cause side effects, although not everybody gets them. Older patients tend to be more likely to suffer from some of these effects than younger patients and this may mean your treatment is supervised more closely.

Serious side effects Stop taking Depixol and seek medical advice immediately if you have any of the following allergic reactions:

Not known: frequency cannot be estimated from the available data

- 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:

Very rare: may affect up to 1 in 10,000 people

- 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 Depixol Injection and similar medicines

- Unusual movements of the mouth and tongue as these may 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.
- In rare cases irregular heart beats (arrhythmias) may have resulted in sudden death
- Any yellowing of the skin and the white in the eyes (jaundice); your liver may be affected

Rare: may affect up to 1 in 1,000 people

- 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)

Other side effects:

Side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment.

Very common: may affect more than 1 in 10 people

- Drowsiness
- Dry mouth
- Muscle spasm
- Rigidity of the whole body

Common: may affect up to 1 in 10 people

- Changes in appetite or weight
- Insomnia
- Depression
- Nervousness or agitation
- Dizziness
- Headaches
- Reduction in your sex drive
- Poor concentration
- Blurred or abnormal vision
- Throbbing or fast heartbeats
- Shortness of breath
- Increase of saliva
- Vomiting
- Indigestion
- Diarrhoea
- Increased sweating or greasy skin
- Itching
- Muscle pain
- Tremor
- Abnormal urination (such as decrease in frequency or amount)
- General weakness or pain, tiredness or feeling unwell

Uncommon: may affect up to 1 in 100 people

- Confusion
- Loss of co-ordination or altered muscle movements (including unusual movements of the mouth, tongue and eyeballs)
- Speech problems
- Fits
- Low blood pressure
- Hot flushes
- Stomach pain
- Feeling sick
- Flatulence (wind) and constipation
- Abnormal liver function tests
- Rashes or skin reactions (including sensitivity to sunlight)
- Stiff and floppy muscle
- Problems with ejaculation or erections in male
- Skin reactions at injection site

Rare: May affect up to 1 in 1,000 people

- 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)
- Reduction in blood platelets (which increases the risk of bleeding or bruising) and other blood cell changes
- Raised blood levels of glucose or the hormone prolactin.
- Loss of control of blood sugar levels
- Breast enlargement in male
- Unexpected excretion of breast milk
- Women may experience an absence of menstrual periods

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

- Slow heartbeat and abnormal ECG heart tracing.
- Life threatening irregular heart beats.

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

5. How to store Depixol Injection

Usually 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. 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 Depixol Injection contains

The active substance is flupentixol decanoate.

Each millilitre (ml) of Depixol Injection contains 20 mg flupentixol decanoate.

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

What Depixol Injection looks like and contents of the pack

Depixol Injection is a clear, colourless or pale-yellow liquid.

Depixol Injection is available in:

Glass ampoules containing 1 ml (20 mg) or 2 ml (40 mg) in cartons of 10 ampoules.

Marketing Authorisation Holder

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

Lundbeck Limited
Iveco House,
Station Road,
Watford,
Hertfordshire,
WD17 1ET,
UK

Manufacturer

H. Lundbeck A/S
Ottiliavej 9
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
Depixol Injection	PL 00458/0007R

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

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The following information is intended for healthcare professionals only:

Administration information for the healthcare professional

Depixol 20 mg/ml solution for injection

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

Depixol 20 mg/ml solution for injection should be administered by deep intramuscular injection into the upper outer buttock or lateral thigh.

The maximum single dose at any one time is 400 mg. For example, 800 mg every 2 weeks should not be given.

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 Depixol Injection range.

It should not be mixed with any other injection fluids.