

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986 The dispensing of this medicine requires a doctor's prescription	
FLUANXOL DEPOT 100 MG/ML Solution for I.M injection	FLUANXOL DEPOT 20 MG/ML Solution for I.M injection

Composition:
1 ml of oily solution for intramuscular injection contains 20mg or 100 mg of flupentixol decanoate.

Inactive ingredients and allergens - see section 6 for further information.

Read all of this leaflet carefully before you start using the medicine

- This leaflet contains essential information regarding this medicine. If you have any further questions, ask the doctor or the pharmacist.
- This medicine has been prescribed for the treatment of your illness. Do not pass it on to others. It may harm them, even if it seems to you that they have the same illness as yours.
- The medicine is not recommended for children and adolescents.

1. WHAT THIS MEDICINE IS USED FOR

Fluanxol Depot 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.
Fluanxol Depot is used for the treatment of schizophrenia and mania.
Therapeutic group: Antipsychotic medicines - derivatives of thioxanthene

2. BEFORE YOU USE THIS MEDICINE

Do not use this medicine <ul style="list-style-type: none">• If you are hypersensitive (allergic) to the active ingredient or any of the other ingredients of this medicine listed in section 6.• If you have diminished consciousness.

Special warnings that relate to the use of the medicine
Do not use this medicine without consulting a physician before starting treatment if you:

- suffer or have suffered in the past from a liver problem
- suffer or have suffered in the past from convulsions or fits (epilepsy).
- have diabetes (An adjustment of the antidiabetic medicines dosages may be required)
- suffer or have suffered in the past from organic brain syndrome (a decrease in the activity of the nervous system that may be a resulting condition after poisoning with alcohol)
- have risk factors for stroke (e.g. smoking, hypertension)
- suffer or have suffered in the past from hypokalemia or hypomagnesia (too little potassium or magnesium in your blood), or have a genetic predisposition for any of these
- suffer or have suffered in the past from cardiovascular disorders
- take or used to take other antipsychotic medicines
- feel nervousness or overactive than normal, since this medicine may increase these feelings
- 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
- Are treated for cancer

If you take other medicines, or if you took lately, other medicines including non-prescription drugs and food-additives, tell your doctor or pharmacist about it. You should inform the doctor or the pharmacist especially if you take or have recently taken any of the following medicines:

- Tricyclic antidepressant medicines
- Medicines used to lower the blood pressure (e.g. Guanethidine and Clonidine)
- Barbiturates (sleeping and sedative medicines)
- Medicines used to treat epilepsy
- Medicines used to treat Parkinson's disease (e.g. Levodopa)
- Metoclopramide (used in the treatment of gastro-intestinal disorders)
- Piperazine (used in the treatment of worms in the gastro-intestinal system).
- Medicines that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known to increase the concentration of Fluanxol Depot in your blood

The following medicines should not be taken at the same time as Fluanxol Depot:

- Medicines that change the heart rate: quinidine, amiodarone, sotalol, dofetilide, erythromycine, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium.
- Other antipsychotic medicines

Drinking alcohol
Fluanxol Depot may increase the sedative effects of alcohol, therefore it is recommended not to drink alcohol during treatment with this medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, or 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, consult a doctor before taking this medicine. Fluanxol Depot should not be used during pregnancy unless clearly necessary. The general condition of your newborn baby might be affected by the use of this medicine during pregnancy.
The following symptoms may occur in newborn babies of mothers that have used Fluanxol Depot in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing and feeding difficulties.
If your baby develops any of these symptoms you may need to contact your doctor.

Breast-feeding
If you are breastfeeding, ask your doctor for advice before taking the medicine. You should not use Fluanxol Depot when breast-feeding, as small amounts of the medicine pass into the breast milk.

Fertility
Animal studies have shown that Fluanxol Depot affects the fertility. Please ask your doctor for advice.

Driving
Do not drive or use dangerous machines during the treatment with Fluanxol Depot, since this medicine may cause drowsiness or dizziness.

3. HOW TO USE THIS MEDICINE
Directions for use and dosage
Always take Fluanxol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This medicine is an intramuscular injection (to the buttock muscle). It should be given by a nurse or a doctor

The frequency of the administration and the dosage are according to doctor's instructions only.

A small volume of Fluanxol Depot is drawn up into a syringe and then injected into muscle of your buttock.

Your doctor will decide on the correct volume of medicine to give, and how often to give it. The medicine is slowly released from the injection that you received in your buttock such that a fairly constant amount of medicine gets into your blood during the period in between injections.

The recommended dose is:

Adults
Fluanxol Depot 20 mg/ml
Usually it will be 1-2 ml and the interval between injections will usually be 1 to 4 weeks.
If you need more than 2 ml of medicine it will probably be divided between 2 injection sites.

Fluanxol Depot 100 mg/ml
Usually it will be 1 ml (but may vary between 0.5 ml and 4 ml) and the interval between injections will usually be 1 to 4 weeks.
If you need more than 2 ml of medicine it will probably be divided between 2 injection sites.

If you have been treated with Fluanxol **tablets** and you are being transferred to Fluanxol Depot 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.

Older people (above 65 years) and Patients with liver problems normally receive doses in the lower end of the dosage range.

Use in Children
Fluanxol Depot is not intended for children and infants.

Do not take more than the recommended dose.

If you have the impression that the effect of Fluanxol Depot is too strong or too weak, talk to your doctor

Duration of treatment
It is important that you continue to receive your medicine at regular intervals as instructed by the doctor.
Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor or the pharmacist. If you stop your treatment too soon your symptoms may return.
Your doctor decides the duration of treatment.

If you get more Fluanxol Depot than you should
Your medicine will be given by your doctor /nurse. In the unlikely event that you receive too much Fluanxol Depot you may experience the following symptoms: drowsiness, unconsciousness, muscle movements or stiffness, convulsions, low blood pressure, weak pulse, fast heart rate, pallor, restlessness, high or low body temperature.

Changes in heart rate including irregular heart beat or slow heart rate has been seen when Fluanxol Depot has been given in overdose together with medicines known to affect the heart.

Symptomatic and supportive treatment will be initiated by the doctor or the nurse.

Continue the treatment for as long as your doctor recommended.

Even if your medical situation has improved, do not stop taking the medicine without consulting a doctor.

Do not take medicines in the dark! Check the label and the dose each time you take your medicine. Wear glasses if you need them.

For further questions about how to use the medicine, ask your doctor or a pharmacist.

4. SIDE EFFECTS

Like all medicines, Fluanxol Depot can cause side effects in some patients. Do not be alarmed by reading the list of side effects. It is possible that you may not suffer from any of them.

You should contact your doctor or go to the hospital straight away if you experience any of the following symptoms:

Uncommon (Side effects that appear in 1-10 persons out of 1000):
Unusual movements of the mouth and tongue (this may be an early sign of a condition known as tardive dyskinesia).

Very rare (Side effects that appear in less than 1 out of 10,000 persons):

- High fever, unusual stiffness of the muscles and disorder of your consciousness, especially if occurring with sweating and fast heart Beat (these symptoms may be signs of a rare condition called neuroleptic malignant syndrome which has been reported with the use of different antipsychotics)
- Yellowing of the skin and the white in the eyes this may mean that your liver is affected by the medicine (and a sign of a condition known as jaundice).

Additional Side Effects
The following side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment:

Very common Side Effects (Side effects that appear in more than one out of ten persons):
Sleepiness, inability to sit still or remain motionless, involuntary movements, slow or diminished movements, dry mouth.

Common Side Effects (Side effects that appear in 1-10 out of 100 persons)
Racing heart rate (tachycardia) or heart beat, tremor, repetitive movements or abnormal postures due to sustained muscle contractions, dizziness, headache, vision disorders, difficulty breathing or painful breathing, increased saliva secretion, constipation, vomiting, digestive problems or discomfort centred in the upper abdomen, diarrhoea, urination disorders, increased sweating, itching, muscle pain, increased appetite, increased weight, fatigue or weakness, Sleeplessness (insomnia), depression, nervousness, agitation, decreased sexual drive (libido decreased).

Uncommon Side Effects (Side Effects that appear in 1-10 out of 1,000 persons):
Involuntary movements of the face and limbs, parkinsonism, speech disorder, convulsion, circular movement of the eyes, abdominal pain, nausea, flatulence, rash, skin reaction due to sensitivity to light, inflammation of the skin(eczema), muscle rigidity, decreased appetite, low blood pressure, hot flush, red or sore skin at the injection site, abnormal liver function tests results, sexual dysfunctions, state of confusion.

Rare Side Effects (Side effects that appear in 1-10 out of 10,000 persons)

- Low blood platelet count (thrombocytopenia), low white blood platelet count (neutropenia), reduced white blood cell count (leukopenia), bone marrow poisoning (agranulocytosis)
- Increased level of prolactin in the blood (hyperprolactinaemia)
- High blood sugar (hyperglycaemia), abnormal glucose tolerance
- Over-sensitivity (hypersensitivity), acute systemic and severe allergic reaction (anaphylactic reaction)
- Development of breasts in men (gynaecomastia), excessive milk production (galactorrhoea), lack of menstrual periods (amenorrhoea)

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

- QT prolongation (slow heart beat and change in the ECG)
- Irregular heart beat
- Torsades de Pointes - a special kind of irregular heart rate

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

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

If a side effect appears, if any of the side effects gets serious, or if you suffer from any side effects not listed in this leaflet, you should consult with the doctor.

5. HOW TO STORE THIS MEDICINE

- Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use the medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.
- **Storage conditions:** Store below 30°C. Keep the ampoules in the original box, so they are protected 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. FURTHER INFORMATION

- **In addition to the active ingredient this medicine also contains:** triglycerides, medium chain
- **What Fluanxol Depot looks like and contents of the pack:**
Fluanxol Depot is a clear, colourless or pale-yellow liquid.
The medicine is available in two dosages:
20 mg/ml: the pack contains 1ml (20mg) or 2ml (40mg) ampoule.
100 mg/ml: the pack contains 1ml ampoule.
- **Licence Holder and address:** Lundbeck Israel Ltd., 4 Derech Hashalom st , Tel Aviv
- **Manufacturer name and address:** H. Lundbeck A/S, Valby, Denmark
- This leaflet was checked and approved by the MoH in June 2014
- Registration number in the national medicines book of the ministry of health: Fluanxol Depot 20mg/ml 061 27 27548
Fluanxol Depot 100mg/ml 061 28 27550