# PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S5**

FLUANXOL DEPOT 20 mg/ml

**Read all of this leaflet carefully before you start using FLUANXOL DEPOT**

- Keep this leaflet. You may need to read it again
- If you have further questions, please ask your doctor pharmacist, nurse or other health care provider
- FLUANXOL DEPOT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet:**


1. What Fluanxol Depot is and what it is used for
2. What you need to know before you use Fluanxol Depot
3. How to use Fluanxol Depot
4. Possible side effects
5. How to store Fluanxol Depot
6. Contents of the pack and other information


## 1. WHAT FLUANXOL DEPOT IS AND WHAT IT IS USED FOR

Fluanxol Depot contains the active substance flupentixol decanoate.

**How FLUANXOL DEPOT works**

FLUANXOL DEPOT belongs to a group of medicines known as antipsychotics (also called neuroleptics).

**Indications**

FLUANXOL DEPOT is used for the treatment of schizophrenia.

## 2. What you need to know before you use FLUANXOL DEPOT

FLUANXOL DEPOT should not be administered to you:

- If you are allergic (hypersensitive) to flupenthixol or any of the other ingredients of FLUANXOL DEPOT (see WHAT FLUANXOL DEPOT CONTAINS). Consult your doctor if you think you might be allergic
- If you are more excited or overactive than normal, since this medicine may increase these feelings
- If you have diminished consciousness
- If you have a phaeochromocytoma
- If you have suppression of the bone marrow.

**Warnings and precautions**

**Tell your doctor or nurse before being given the injection**

- If you have a liver problem
- If you have a history of convulsions or fits
- If you have diabetes (you may need an adjustment of your antidiabetic therapy)
- If you have an organic brain syndrome (which may be the result of poisoning with alcohol or organic solvents)
- If you have risk factors for stroke (e.g. smoking, hypertension)
- If you have hypokalaemia or hypomagnesaemia (too little potassium or magnesium in your blood or genetic predisposition for any of these)
- If you have a history of cardiovascular disorders
- If you use any other antipsychotic medicine
- If you or someone else in your family has a history of blood clots, as medicines like FLUANXOL DEPOT have been associated with formation of blood clots.
- If you are an elderly person with dementia-related behavioural disturbances.

Please consult your doctor, even if these statements were applicable to you at any time in the past.

**Other medicines and Fluanxol depot**

**If you are taking or using other medicines on a regular basis, including complementary or traditional medicines, the use of FLUANXOL DEPOT with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare provider for advice.**

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

- Tricyclic antidepressant medicines
- Medicines used to lower the blood pressure
- Barbiturates (medicines that make you feel drowsy)
- Medicines used to treat epilepsy
- Levodopa and similar medicines (used to treat Parkinson's disease)
- Metoclopramide (used in the treatment of gastro-intestinal disorders)
- Piperazine (used in the treatment of roundworm and threadworm infections)
- 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 heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, gatifloxacin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines.

**FLUANXOL DEPOT with alcohol**

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

**Pregnancy, breastfeeding and fertility**

FLUANXOL DEPOT should not be used during pregnancy or breastfeeding.

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| If you are pregnant or breastfeeding your baby while having FLUANXOL DEPOT, please consult your doctor, pharmacist or other healthcare provider for advice. |

**Pregnancy**

The general condition of your newborn baby might be affected by FLUANXOL.

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 problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

**Breastfeeding**

You should not use FLUANXOL DEPOT when breastfeeding, as small amounts of the medicine can pass into the breast milk.

If you are given FLUANXOL DEPOT you should not breastfeed your baby.

**Driving and using machines**

There is a risk of feeling drowsy and dizzy when using FLUANXOL DEPOT. If this happens, do not drive or use any tools or machines until these effects wear off.

**3. How to use FLUANXOL DEPOT**

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself this medicine. It will be given to you by a person qualified to do so.

**How and when to receive FLUANXOL DEPOT**

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.

**Adults**

Usually 1-3 ml will be administered and the interval between injections will usually be 2 to 4 weeks.

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

If you have the impression that the effect of FLUANXOL DEPOT is too strong or too weak, talk to your

doctor or pharmacist.

Your doctor decides the duration of treatment.

**If you receive more FLUANXOL DEPOT than you should**

**In the event of overdosage, consult your doctor or pharmacist.**
**If neither is available, contact the nearest hospital or poison centre.**

If you receive too much FLUANXOL DEPOT, you may experience certain symptoms

Symptoms of overdose may include:

- Drowsiness
- Unconsciousness
- Muscle movements or stiffness
- Convulsions
- Low blood pressure, weak pulse, fast heart rate, pallor, restlessness
- High or low body temperature
- Changes in heartbeat 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.

**If you have missed a dose of FLUANXOL DEPOT**

You should not receive a double dose to make up for missed individual doses.

**4. Possible side effects**

FLUANXOL DEPOT can cause side effects.

Not all side effects reported for FLUANXOL are included in leaflet. Should your general health worsen or if you experience any untoward effects while taking FLUANXOL, please consult your health care provider for advice.

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

Less frequent:

- Unusual movements of the mouth and tongue; this may be an early sign of a condition known as tardive dyskinesia.
- High fever, unusual stiffness of the muscles and disorder of your consciousness, especially if occurring with sweating and fast heart rate; these symptoms may be signs of a condition called neuroleptic malignant syndrome.
- Yellowing of the skin and the white in the eyes, this may mean that your liver is affected and a sign of a condition known as jaundice.

Frequent:

- Sleepiness (somnolence), inability to sit still or remain motionless (akathisia), involuntary movements (hyperkinesia), slow or diminished movements (hypokinesia)
- Dry mouth.
- 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), dizziness, headache
- Difficulties focusing on objects near to the eye (accommodation disorder), vision abnormalities
- Difficulty breathing or painful breathing (dyspnoea)
- Increased saliva secretion (salivary hypersecretion), constipation, vomiting, digestive problems or discomfort centered in the upper abdomen (dyspepsia), diarrhoea
- Urination disorder (micturition disorder), lack of ability to urinate (urinary retention)
- Increased sweating (hyperhidrosis), itching (pruritus)
- Muscle pain (myalgia)
- Increased appetite, increased weight
- Fatigue, weakness (asthenia)
- Sleeplessness (insomnia), depression, nervous-ness, agitation, decreased sexual drive (libido decreased).

Less frequent:

- Jerky movements (dyskinesia), parkinsonism, speech disorder, convulsion
- Circular movement of the eye (oculogyration)
- Abdominal pain, nausea, flatulence

- Rash, skin reaction due to sensitivity to light (photosensitivity reaction), eczema or inflammation of the skin (dermatitis)
- Muscle rigidity
- Decreased appetite
- Low blood pressure (hypotension), hot flushes
- Abnormal liver function tests
- Sexual disturbance (delayed ejaculation, problems with erection)
- State of confusion.
- 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
- Oversensitivity (hypersensitivity), acute systemic and severe allergic reaction (anaphylactic reaction)
- Development of breasts in men (gynaecomastia), excessive milk production (galactorrhoea), lack of menstrual periods (amenorrhoea).
- QT prolongation (slow heart beat and change in the ECG)
- Irregular heart beat (ventricular dysrhythmias, ventricular fibrillation, ventricular tachycardia)
- Torsades de Pointes (a special kind of irregular heartbeat).
- Irregular heartbeats (dysrhythmias) 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, an increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

If you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help

provide more information on the safety of FLUANXOL DEPOT.

**5. How to store FLUANXOL DEPOT**

Usually your doctor or nurse will store this medicine. Should you be required to keep it at home:

- Keep out of the reach and sight of children
- Do not use FLUANXOL DEPOT after the expiry date, which is stated on the label. The expiry date refers to the last day of that month
- Store FLUANXOL DEPOT at or below 30 ºC
- Keep FLUANXOL DEPOT ampoules in the box, so they are protected from light
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required
- These measures will help to protect the environment.

**6. Contents of the pack and other information**

**What Fluanxol Depot contains**

The active substance is flupentixol decanoate.

Each millilitre (ml) of Fluanxol Depot contains 20 mg or 100 mg flupentixol decanoate.

The other ingredient is thin vegetable oil (triglycerides, medium chain).

**What Fluanxol Depot looks like and contents of the pack**

FLUANXOL DEPOT is available in colourless glass ampoules containing 1 ml (20 mg). The 1 ml ampoule is available in boxes of 1 or 5.

FLUANXOL DEPOT is a clear, colourless to slightly yellowish oil, practically free from particles.

**REGISTRATION NUMBERS**

G/2.6.5/138

**HOLDER OF CERTIFICATE OF REGISTRATION**

Adcock Ingram Limited

1 New Road

# PATIENT INFORMATION LEAFLET

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

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