

# FLUTHIXOL INJECTION

20 mg/ml, 40mg/2ml

(Flupentixol Decanoate BP)

**Composition:**

Each ml contains:  
Flupentixol Decanoate BP.....20mg  
(Product complies BP specification)

**1. What Flupentixol decanoate is and what it is used for:-**

Flupentixol decanoate 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.  
Flupentixol decanoate is used for the treatment of schizophrenia and other related psychoses.  
Your doctor, however, may prescribe Flupentixol decanoate for another purpose. Ask your doctor if you have any questions about why Flupentixol decanoate has been prescribed for you.

**2. What you need to know before you use Flupentixol decanoate:-**

Do not use Flupentixol decanoate  
- If you are allergic (hypersensitive) to flupentixol.  
- If you have diminished consciousness.

**Warnings and precautions:-**

Talk to your doctor or pharmacist before taking Flupentixol decanoate if you  
- have a liver problem  
- have a history of convulsions or fits  
- have diabetes (you may need an adjustment of your antidiabetic therapy)  
- have an organic brain syndrome (which may be a resulting condition after poisoning with alcohol or organic solvents)  
- have risk factors for stroke (e.g. smoking, hypertension)  
- have hypokalemia or hypomagnesia (too little potassium or magnesium in your blood or genetic predisposition for any of these)  
- have a history of cardiovascular disorders  
- use other antipsychotic medicine  
- are more excited or overactive than normal, since this medicine may increase these feelings  
- 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:-**

Flupentixol decanoate is not recommended in this patient group.

**Other medicines and Flupentixol decanoate:-**

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

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

- Tricyclic antidepressant medicines
  - Guanethidine and similar 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 gastrointestinal 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 Flupentixol decanoate in your blood
- The following medicines should not be taken at the same time as Flupentixol decanoate:
- Medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, cisapride, lithium)
  - Other antipsychotic medicines

**Flupentixol decanoate with alcohol:-**

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

**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 for advice before taking this medicine.

**Pregnancy:-**

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

The following symptoms may occur in new born babies, of mother that have used Flupentixol decanoate 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. You should not use Flupentixol decanoate when breast-feeding, as small amounts of the medicine can pass into the breast milk.

**Fertility:-**

Animal studies have shown that Flupentixol decanoate affects the fertility.

**Driving and using machines:-**

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

**3. How to use Flupentixol decanoate:-**

A small volume of Flupentixol decanoate 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**

Flupentixol decanoate 20mg/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 2ml of medicine it will probably be divided between 2 injection sites.

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

**Older people (above 65 years)**

Are usually treated with doses in the lower end of the dosage range.

**Patients with special risks**

Patients with liver complaints normally receive doses in the lower end of the dosage range.

**Use in Children:-**

Flupentixol decanoate is not recommended for children.

If you have the impression that the effect of Flupentixol decanoate 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 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.

Your doctor decides the duration of treatment.

**If you get more Flupentixol decanoate than you should:-**

Your medicine will be given by your doctor/nurse. In the unlikely event that you receive too much Flupentixol decanoate you may experience some 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 heart beat including irregular heart beat or slow heart rate has been seen when Flupentixol decanoate has been given in overdose together with medicines known to affect the heart
- Symptomatic and supportive treatment will be initiated by your doctor/nurse.

**4. Possible side effects:-**

Like all medicines, Flupentixol decanoate can cause side effects, although not everybody gets them.

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

Uncommon (in more than 1 out of 1,000 and less than 1 out of 100 persons):

- Unusual movements of the mouth and tongue; this may be an early sign of a condition known as tardive dyskinesia.

Very rare (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 rate; these symptoms 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 and a sign of a condition known as jaundice

**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 (in 1 or more out of 10 persons):

- Sleepiness (somnolence), inability to sit still or remain motionless (akathisia), involuntary movements (hyperkinesia), slow or diminished movements (hypokinesia)
- Dry mouth

Common (in more than 1 out of 100 persons and less than 1 out of 10 persons):

- 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)

**Presentation :**

- Injection 1ml-Fluthixole 20mg glass ampoule in a Pack of 1's.
- Injection 2ml-Fluthixole 40mg glass ampoule in a Pack of 1's.

**Dosage :** As directed by the physician.

**Instructions :** Store below 30°C.

Protect from heat & light.

Keep all medicines out of the reach of children.

To be sold on prescription of a registered medical practitioner only.

Manufactured by:  
**PHARMEDIC LABORATORIES (PVT) LIMITED.**  
16 Km. Multan Road, Lahore - Pakistan