

# FLUANXOL<sup>®</sup> TABLET

Flupentixol (as flupentixol dihydrochloride) (0.5mg)

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## What Fluanxol is used for

Fluanxol is used to treat depression in patients who may, or may not also be showing signs of anxiety.

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

## How Fluanxol works

Fluanxol contains the active substance flupentixol. Fluanxol belongs to a group of medicines that work by correcting chemical imbalances in the brain, and thereby relieving the symptoms of depressed mood.

## Before you use Fluanxol

### - When you must not use it

Do not take Fluanxol

- If you are allergic (hypersensitive) to flupentixol or to any of the other ingredients of this medicine (listed in **Product Description**)
- If you have diminished consciousness, or serious problems with your blood circulation
- If you have a severe depression, for example if you are required to stay in hospital or requiring electroconvulsive therapy (ECT).

### - Before you start to use it

Talk to your doctor or pharmacist before taking Fluanxol if you:

- have a liver or kidney 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 heart or cardiovascular disorders
- are more excited or overactive than normal (mania), 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
- have a history of suicide-related event

### *Pregnancy and breast feeding*

Tell your doctor if you are pregnant, think that you may be pregnant or are planning to become pregnant. Do not take Fluanxol until you and your doctor have discussed the risks and benefits involved.

The following extrapyramidal and/or withdrawal symptoms may occur in newborn babies, of mothers that have used Fluanxol in the last trimester (last three months of their pregnancy): agitation, muscle stiffness and/or weakness, shaking, sleepiness, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Do not use this medicine if you are breast-feeding. This is because small amounts may pass into the mother's milk.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

### *Fertility*

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

## - Taking other medicines

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 (fits)
- 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), such as certain diuretics
- Medicines known to increase the concentration of Fluanxol in your blood

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

- Medicines that change the heartbeat (e.g. quinidine, amiodarone, sotalol, dofetilide)
- Certain medicines used to treat infections (e.g. erythromycin, gatifloxacin, moxifloxacin)
- Medicines used to relieve the symptoms of allergy (e.g. terfenadine, astemizole)
- Cisapride (used to treat stomach problems)
- Lithium, medicines used to treat certain mental illness
- Other antipsychotic medicines

### *Fluanxol with food, drink and alcohol*

- Fluanxol can be taken with or without food.
- Fluanxol may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment with Fluanxol.

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Other medicines not listed above may also interact with Fluanxol.

## How to use Fluanxol

Always take Fluanxol exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

### - How much to use

#### Adults

The usual starting dose is 1 mg per day. After a week your doctor may increase this to 2 mg per day. The maximum dose is 3 mg per day.

#### Older people (above 65 years)

The usual starting dose is 0.5 mg. After a week your doctor may increase this to 1 mg per day. The maximum dose is 1.5 mg per day.

#### Use in children

Fluanxol is not recommended for children.

### - When to use it

Swallow the tablets with a drink of water. Do not chew them.

Fluanxol is usually taken as a single daily dose in the morning.

Doses higher than 2 mg per day in adults (and 1 mg in the elderly) should be divided into a morning dose and an afternoon dose.

### - How long to use it

Patients often respond to Fluanxol treatment quite quickly, but if you have been taking the maximum dose for a week or so and still do not feel better, your doctor may decide to stop the treatment. Your doctor decides the duration of treatment. Continue to take the tablets for as long as your doctor recommends. Never change the dose of the medicine without talking to your doctor first.

### - If you forget to use it

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten tablet.

### - If you use too much (overdose)

If you think that you or anyone else may have taken too many Fluanxol tablets

contact your doctor or nearest hospital casualty department immediately. Do this even if there are no signs of discomfort or poisoning. Take the Fluanxol container with you if you go to a doctor or hospital.

Symptoms of overdose may include:

- Drowsiness
- Unconsciousness
- Problems with muscle movement
- 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 Fluanxol has been given in overdose together with medicines known to affect the heart

## While you are using it

### - Things you must do

Read all of this leaflet carefully before you start taking this medicine

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. (See **Side effects**)
- If you have the impression that the effect of Fluanxol is too strong or too weak, talk to your doctor.

### - Things you must not do

Do not stop taking Fluanxol even if you begin to feel better, unless you are told to do so by your doctor. Your doctor will gradually reduce the amount you take each day before stopping the medicine completely. If you stop taking Fluanxol suddenly, your condition may worsen or you may have unwanted side effects such as nausea, vomiting, anorexia (an eating disorder characteristics by self-starvation and excessive weight loss), diarrhea, rhinorrhea (runny nose), sweating, myalgias (muscle aches), paraesthesias (tingling or prickling sensation on skin), insomnia, restlessness, anxiety and agitation. You may also experience vertigo,

alternate feelings of warmth and coldness, and tremor.

If you have any further questions on the use of this product, ask your doctor or pharmacist. 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.

### - Things to be careful of

#### *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.

#### *Driving and using machines*

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

#### *Fluanxol contains lactose and sucrose*

If your doctor has told you that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

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## Side effects

Like all medicines, Fluanxol 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 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 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)
- Sleeplessness (insomnia), depression, nervousness, agitation, decreased sexual drive (libido decreased)

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

- 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 flush
- Abnormal liver function tests
- Sexual disturbance (delayed ejaculation, problems with erection)
- State of confusion

*Rare (more than 1 out of 10,000 and less than 1 out of 1,000 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 flupentixol (the active ingredient of Fluanxol), rare cases of the following side effects have been reported:

- QT prolongation (slow heart beat and change in the ECG)
- Irregular heart beat (ventricular arrhythmias, ventricular fibrillation, ventricular tachycardia)
- Torsades de Pointes (a special kind of irregular heart beat)

In rare cases irregular heart beats (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 (loss of mental ability severe enough to interfere with normal daily activities), a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Other side effects not listed above may occur in some patients. Tell your doctor and pharmacist if you notice anything else that is making you feel unwell, even if it is not on this list.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

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## Storage and Disposal of Fluanxol

47301 Petaling Jaya

### - *Storage*

Keep this medicine out of the reach and sight of children.

This medicinal product does not require any special storage conditions.

### **Date of Revision**

28/10/2015

### **Serial Number**

BPFK(R4/1)300915/00330

### - *Disposal*

Do not use this medicine after the expiry date, which is stated on the label. The expiry date refers to the last day of that month.

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.

## Product Description

### - *What it looks like*

The 0.5 mg coated tablets are round, biconvex, ochre-yellow.

Fluanxol coated tablets are available in containers: 100 tablets

### - *Ingredients*

#### • *Active ingredient:*

The active substance is flupentixol (as hydrochloride).

Each Fluanxol coated tablet contains 0.5 mg flupentixol.

#### • *Inactive ingredient:*

The other ingredients are lactose monohydrate, potato starch, gelatine, talc, magnesium stearate.

*Coating:* Gelatine, sucrose, sucrose powder. Wax polish - a mixture of white wax and carnauba wax.

*Colour:* Yellow iron oxide (E 172).

### - *MAL number:*

MAL19890543A

## Manufacturer

H. Lundbeck A/S  
Ottiliavej 9  
2500 Valby  
Denmark

## Product Registration Holder

Lundbeck Malaysia Sdn. Bhd.  
A-05-01, Oasis Square,  
Jalan PJU 1A/7A, Ara Damansara,