

Fluanxol

Notice: user information

Fluanxol 1 mg film-coated tablets

flupentixol

Please read this leaflet carefully before taking 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 or pharmacist.
- This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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1. WHAT IS FLUANXOL AND WHAT IS IT USED FOR?

Fluanxol contains the active ingredient flupentixol. Fluanxol belongs to a group of medicines called antipsychotics (also called neuroleptics), which can also treat the symptoms of depression.

These medications act on the nerve pathways in specific parts of the brain and help restore certain chemical imbalances in the brain that are causing the symptoms of your illness.

Fluanxol is used for the treatment of mild to moderate depressive episodes, with or without anxiety or somatic complaints.

Fluanxol is used for the treatment of mental disorders in schizophrenia and other psychotic conditions, such as delusions, hallucinations, illusions, and thought disorders, as well as the associated withdrawn behavior and apathy.

However, your doctor may prescribe Fluanxol for another cause. If you have any questions about how to use Fluanxol for you, please consult your doctor.

2. WHAT YOU NEED TO KNOW BEFORE TAKING FLUANXOL?

Never take Fluanxol

- If you are allergic to flupentixol or any of the other ingredients of this medicine (listed in section 6).
- Hypotension with loss of consciousness (circulatory collapse).
- If you are in a state of diminished consciousness regardless of the cause.
- Comatose state.

Fluanxol tablets are not indicated if you suffer from severe depression, e.g. if hospitalization or electroconvulsive therapy (ECT) is required.

Warnings and precautions

Talk to your doctor or pharmacist before taking Fluanxol.

- If you have liver disease.
- If you have a history of seizures or convulsions.
- If you are diabetic (in this case, your doctor may adjust your antidiabetic therapy).
- If you have brain damage (which may be caused by alcohol or organic solvent poisoning).
- If you have risk factors for a stroke (e.g., smoking, high blood pressure).
- If you have hypokalemia or hypomagnesemia (too little potassium or magnesium in your blood) or if you show a genetic predisposition for either of these.
- If you have a history of heart or blood vessel disease.
- If you are taking other antipsychotic medications (for mental illness).
- If you are more excited than usual or much more active, as this medicine may enhance these feelings/behaviors.
- If you, or anyone in your family, has a history of blood clots, as blood clots have been linked to these types of medications.

Children and adolescents

Fluanxol is not recommended for this group of patients.

Suicidal thoughts and worsening of your depression or anxiety disorder

If you suffer from depression and/or anxiety disorders, you may occasionally experience thoughts of self-harm or suicide. These thoughts may be heightened when you first start antidepressant treatment because these medications take time to work, usually about two weeks, but sometimes longer.

You are more likely to experience such thoughts:

- If you have previously had thoughts of suicide or self-harm.
- If you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behavior in adults under 25 years of age with psychiatric disorders who were treated with an antidepressant.

If you have thoughts of suicide or self-harm at any time, **contact your doctor or go to the hospital directly.**

You may find it helpful to tell a family member or friend that you are suffering from depression or an anxiety disorder, and ask them to read this leaflet. You could ask them to alert you if they think your depression or anxiety is getting worse, or if changes in your behavior worry them.

Other medicines and Fluanxol

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

If you are taking any of the following medicines, talk to your doctor:

- Tricyclic antidepressants
- Guanfacine and similar drugs (used to lower blood pressure)
- Barbiturates (drowsiness-causing drugs)
- Medications for epilepsy
- Levodopa and similar products (used to treat Parkinson's disease)
- Metoclopramide (used to treat gastrointestinal disorders)
- Piperazine (used to treat roundworm infections)
- Medications that disrupt the water and salt balance in the body (too little potassium or magnesium in the blood)
- Medicines that may increase the amount of Fluanxol in your blood.

The following medications cannot be used at the same time as Fluanxol:

- Drugs that can alter heart rhythm (e.g., quinidine, amiodarone, sotalol, dofetilide, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium).
- Other antipsychotic drugs (for mental illnesses).

Fluanxol and alcohol

Fluanxol can be taken with or without food.

Fluanxol can enhance the sedative effect of alcohol and make you more drowsy. For this reason, it is advisable not to drink alcohol while taking Fluanxol.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

Fluanxol will not be used during pregnancy unless strictly necessary.

The following symptoms may occur in newborns of mothers who have used Fluanxol during the last trimester (the last three months of their

pregnancy): tremors, muscle stiffness and/or weakness, drowsiness, agitation, breathing problems and difficulty feeding. If your baby experiences any of these symptoms, it is advisable to contact your doctor.

Breastfeeding

If you are breastfeeding, consult your doctor. Fluanxol should not be used if you are breastfeeding, as it is found in small amounts in breast milk.

Fertility

Animal studies have shown that Fluanxol may affect fertility. Consult your doctor for advice.

Driving and using machines

When using Fluanxol, there is a risk of feeling drowsy or dizzy. If this happens, do not drive or operate machinery until these symptoms have passed.

Fluanxol contains sodium and lactose

This medicinal product contains less than 1 mmol (23 mg) sodium per film-coated tablet, i.e. essentially 'sodium-free'.

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

3. HOW TO TAKE FLUANXOL?

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are unsure.

The amount of product to be administered depends mainly on the patient's clinical condition. The doctor will always strive to prescribe the lowest effective dose.

Fluanxol can be taken with or without food.

Swallow the tablets with liquid or water without chewing.

Fluanxol is usually taken once a day in the morning. A dose of more than 2 mg per day (and 1 mg for the elderly) should be divided into 2 to 3 doses per day. During maintenance treatment, Fluanxol can be taken once a day.

The recommended dose is:

Adults

Mild to moderate depressive episodes

Starting dose: 1 mg daily, once daily in the morning or 0.5 mg twice daily. If insufficient clinical effect is seen after one week, the dose may be increased to 2 mg daily. Daily doses exceeding 2 mg should be spread throughout the day up to a maximum of 3 mg daily.

Patients usually respond within 2 to 3 days. If there is no effect after one week at the maximum dose, this medication should be discontinued.

Schizophrenia and other psychoses

Starting dose: Normally 3 to 15 mg per day in 2 to 3 doses. If necessary, increase gradually to a maximum of 40 mg per day. Maintenance dose: Usually between 5 and 20 mg per day.

Oral treatment with Fluanxol can be replaced by treatment with Fluanxol Depot.

Elderly patients (over 65 years)

Generally, older patients are given a lower dose.

Patients at specific risk

In general, people with liver problems receive a lower dose.

Use in children

It is not recommended to administer Fluanxol to children.

If you feel that Fluanxol is too strong or too weak for you, talk to your doctor.

Duration of treatment

Mild and moderate depressive episodes

Most often, patients respond very quickly to treatment with Fluanxol, but if you do not feel better after a week of treatment at the maximum dose, the doctor may decide to stop treatment with this medicine.

Schizophrenia and other psychoses

As with other medications used to treat psychoses, it may take a few weeks before you feel any improvement.

Your doctor will decide how long you should take the tablets. Continue taking the tablets for as long as your doctor advises. Your underlying condition may persist for some time, and if you stop too soon, symptoms may return.

Never change the dose without first consulting your doctor.

If you take more Fluanxol than you should

If you have taken too much Fluanxol, or in case you have discovered that someone has taken too much Fluanxol, immediately contact your doctor, pharmacist or the Poison Control Center (070/245 245), or the nearest hospital emergency department, even if you do not feel any discomfort or show signs of poisoning. Take your Fluanxol pill box with you if you go to the doctor or hospital.

Signs that might indicate that Fluanxol has been taken in too high a dose could include:

- Drowsiness
- Loss of consciousness
- Muscle contractions or stiffness
- Convulsions
- Low blood pressure, weak pulse, rapid heart rate, paleness, agitation
- High or low body temperature
- Changes in heart rhythm, including irregular or slower heart rate when Fluanxol has been taken in overdose with other medicines that affect the functioning of the heart.

If you forget to take Fluanxol

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 dose.

If you stop taking Fluanxol

Do not stop taking Fluanxol yourself, even when you start to feel better, unless your doctor has told you to stop.

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

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the symptoms listed below, you should consult your doctor or go to the hospital immediately.

Uncommon (may affect up to 1 in 100 people)

- Unusual mouth and tongue movements. These may be an early sign of a condition called tardive dyskinesia.

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

- High fever, unusual muscle rigidity with impaired consciousness, especially if accompanied by sweating and a rapid heart rate. These symptoms could be signs of a rare condition called neuroleptic malignant syndrome. This has been reported after use of various antipsychotics.
- Yellowish discoloration of the skin and whites of the eyes. May indicate a liver disorder and may be a sign of jaundice.

The following side effects are most pronounced at the beginning of treatment and disappear in most cases with continued treatment.

Very common (may affect more than 1 in 10 people)

- Drowsiness, difficulty staying still or remaining motionless (akathisia), involuntary movements (hyperkinesia), slow or decreased movements (hypokinesia)
- Dry mouth

Common (may affect up to 1 in 10 people)

- Rapid heart rate (tachycardia), sensation of a fast, pounding, or irregular heartbeat (palpitations)
- Tremors, twisting or repetitive movements or abnormal position due to muscle contractions (dystonia), dizziness, headaches
- Difficulty seeing objects that are very close to the eye clearly (accommodation disorders); abnormal vision
- Difficulty or painful breathing (dyspnea)
- Increased salivation (salivary hypersecretion), constipation, vomiting, digestive problems or discomfort in the upper abdomen (dyspepsia), diarrhea
- Problems urinating (micturition disorders), inability to urinate (urinary retention)
- Excessive sweating (hyperhidrosis), itching (pruritus)
- Muscle pain (myalgia)
- Increased appetite, weight gain
- Fatigue, weakness (asthenia)
- Insomnia, depression, nervousness, excitement, decreased sexual desire (decreased libido)

Uncommon (may affect up to 1 in 100 people)

- Spastic movements (dyskinesia), Parkinsonism, speech disorders, seizures
- Rotating eye movements (oculogyric crisis)
- Abdominal (stomach) pain, nausea, flatulence
- Skin rash, skin reaction due to sensitivity to light (photosensitivity reaction), eczema or skin inflammation (dermatitis)
- Muscle stiffness
- Decreased appetite
- Low blood pressure (hypotension), hot flashes
- Disturbed liver function tests
- Sexual problems (delayed ejaculation or erection problems)
- Confusion

Rare (may affect up to 1 in 1,000 people)

- Decreased number of blood platelets (thrombocytopenia), decreased number of white blood cells (neutropenia), decreased number of white blood cells (leukopenia), bone marrow poisoning (agranulocytosis)
- High levels of the hormone prolactin in the blood (hyperprolactinemia)
- High blood sugar (hyperglycemia), impaired glucose tolerance (abnormal glucose tolerance)
- Hypersensitivity, acute systemic reaction and severe allergic reaction (anaphylactic shock)
- Development of breasts in men (gynecomastia), excessive secretion of milk (galactorrhoea), absence of menstrual cycle (amenorrhoea)

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

- QT prolongation (slow heart rate and changes in ECG)
- Irregular heartbeats (ventricular arrhythmias, ventricular fibrillation, ventricular tachycardia)
- Torsades de Pointes (a particular form of irregular heartbeat)

- Cardiac arrest

In a few rare cases, irregular heartbeats (arrhythmias) have been reported to result in sudden death.

Venous blood clots, particularly in the legs (symptoms include swelling, pain, and redness in the legs), which can travel through blood vessels to the lungs, causing chest pain and difficulty breathing. If you experience any of these symptoms, seek medical help immediately.

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

Frequency not known (cannot be estimated from the available data)

Cases of suicidal thoughts and behaviour have been reported during treatment with Fluanxol or very soon after stopping treatment (see section "Warnings and precautions").

Reporting of side effects

If you experience any side effects, talk to your doctor or pharmacist. 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.

Belgium

Federal Agency for Medicines and Health Products

www.afmps.be

Vigilance Division:

Website: www.notifieruneffetindesirable.be

e-mail: adr@fagg-afmps.be

Luxembourg

Regional Pharmacovigilance Centre of Nancy or Pharmacy and Medicines Division of the Health Directorate

Website: www.guichet.lu/pharmacovigilance

5. HOW TO STORE FLUANXOL?

Keep out of sight and reach of children.

This medicine does not require any special storage precautions.

Do not use this medicine after the expiry date shown on the carton and label after "EXP". The expiry date refers to the last day of that month.

Do not dispose of any medications via wastewater or household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What Fluanxol contains

The active ingredient is flupentixol dihydrochloride.
Each tablet contains 1 mg of flupentixol (as dihydrochloride).

The other ingredients are betadex, lactose monohydrate, corn starch, hydroxypropylcellulose, microcrystalline cellulose, croscarmellose sodium, talc, hydrogenated vegetable oil, magnesium stearate.

Coating: OPADRY II 85F38027 yellow (consisting of: hydrolyzed polyvinyl alcohol, macrogol/PEG 3350, yellow iron oxide (E172), talc, titanium dioxide (E171)), macrogol/PEG 6000.

What Fluanxol looks like and contents of the outer packaging

Fluanxol is available as 1 mg film-coated tablets with the following description:
Yellow, oval, slightly biconvex film-coated tablets marked with 'FF'.

Fluanxol film-coated tablets are available in a cardboard box containing 50 tablets in a high-density polyethylene pill box.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:
Lundbeck SA, Stephanie Square Centre, Avenue Louise 65/11, 1050 Brussels

Manufacturer:
H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark.

Marketing Authorization Number:

BE: BE015601
LU: 2007069348

Delivery method: On medical prescription.

The last date this notice was approved is 11/2024.