

FLUANXOL 0.5MG FILM-COATED TABLETS

Flupentixol (as 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 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 section Ingredients)
- If you have diminished consciousness.

Not recommended for excitable or agitated patients

Fluanxol tablets are not suitable 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 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

Children and adolescents

Fluanxol is not recommended in this patient group.

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.

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
- 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 in your blood

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

- Medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium)
- Other antipsychotic medicines

Fluanxol with food, drink and alcohol

- Fluanxol can be taken with or without food.

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- Fluanxol may increase the sedative effects of alcohol making you drowsier. It is recommended not to drink alcohol during treatment 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.

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

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
- 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 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 section Side effects.

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.

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

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. Fluanxol should not be used during pregnancy unless clearly necessary.

The following symptoms may occur in newborn babies, of mothers that have used Fluanxol 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 breastfeeding, ask your doctor for advice. You should not use Fluanxol when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility

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

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 film-coated tablets contains lactose

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

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

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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 heartbeats (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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Fluanxol

Storage

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

Do not store above 30°C.

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

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medicines you no longer use. These measures will help to protect the environment.

Product Description

What it looks like

Fluanxol is presented as 0.5mg film-coated tablets.

The 0.5mg film-coated tablets are round, slightly biconvex, yellow, marked FD.

Ingredients

- Active ingredient:
The active substance is flupentixol (as hydrochloride).
Each Fluanxol film-coated tablet contains 0.5 mg flupentixol.
- Inactive ingredient: The other ingredients are betadex, lactose monohydrate, maize starch, hydroxypropylcellulose, microcrystalline cellulose, croscarmellose sodium, talc, hydrogenated vegetable oil, magnesium stearate

Coating and Colour: marcrogol 6000, polyvinyl alcohol, macrogol, iron oxide yellow(E172), talc, titanium dioxide(E171)

MAL No.: MAL18086153AZ

Manufacturer

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Product Registration Holder

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