

Package leaflet: information for the user
Fluanxol 0.5 mg and 1 mg film-coated tablets
(flupentixol)

Read all of this leaflet carefully before you start 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, pharmacist or nurse.
- 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.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Fluanxol is and what it is used for**
- 2. What you need to know before you take Fluanxol**
- 3. How to take Fluanxol**
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1. What Fluanxol is and what it is used for

Fluanxol contains the active substance flupentixol.

Fluanxol belongs to a group of medicines known as neuroleptics (antipsychotics) that work by relieving the symptoms of depression.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What you need to know before you take Fluanxol

Do not take Fluanxol if you:

- are allergic to flupentixol or any of the other ingredients of this medicine listed in section 6.
- have a reduced level of awareness due to the consumption of alcohol or drugs such as opiates (e.g. morphine) and barbiturates
- are an older person who suffers from confusion
- are a child
- have severe depression.

Warnings and precautions

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

- have a liver problem
- have a kidney problem

- have a history of fits or convulsions or have any condition that might make you prone to fits e.g. head injury, alcohol withdrawal
- have Parkinson's disease
- have a respiratory disease (e.g. asthma or COPD (chronic obstructive pulmonary disease))
- are an older person (you may be at risk of low body temperature (hypothermia), sedation, low blood pressure (hypotension) or confusion
- 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 a heart condition, if anyone in your family has a heart condition or if you are taking medicines that change the heartbeat
- have hypokalaemia or hypomagnesaemia (too little potassium or magnesium in your blood or genetic predisposition for any of these)
- are about to undergo any procedure which will require a general anaesthetic (if this is for dentistry, tell your dentist)
- 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.

Other medicines and Fluanxol

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

Tell your doctor, pharmacist or nurse if you are taking any of the following medicines:

- Tricyclic antidepressant medicines
- Guanethidine, hydralazine and similar medicines (used to lower the blood pressure)
- Alcohol and other medicines that make you drowsy such as barbiturates
- Medicines used to treat epilepsy (e.g. phenytoin, sodium valproate, gabapentin, carbamazepine, lamotrigine)
- 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)
- Digoxin (used in the treatment of heart conditions)
- Corticosteroids (used to treat a range of conditions, including inflammatory diseases)
- Warfarin, ticlopidine, dipyridole and similar medicines called anticoagulants (used to thin the blood)
- Medicines such as diuretics (water tablets) that cause a disturbed water or salt balance (too little potassium or magnesium in your blood)
- Medicines known as non steroidal anti-inflammatory drugs (e.g. ibuprofen, diclofenac, mefenamic acid) and aspirin which are used to relieve pain and to thin the blood)
- Medicines known as phenothiazines used to treat mental illness (e.g. chlorpromazine, fluphenazine).

The following medicines should not be taken with this medicine:

- Medicines that change the heartbeat such as quinidine, amiodarone, sotalol, dofetilide, erythromycin, terfenadine, astemizole, gatifloxacin, moxifloxacin, cisapride, lithium.
- Other antipsychotic medicines (e.g. thioridazine).

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 this medicine.

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 this medicine in the last trimester (last three months of 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 this medicine when breast-feeding, as small amounts of the medicine can pass into the breast milk.

Fertility

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

Driving and using machines

There is a risk of feeling drowsy and dizzy when using this medicine. If this happens, do not drive or use any tools or machines until these effects wear off (see Taking other medicines and Taking Fluanxol with food and drink).

Fluanxol film-coated tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Fluanxol

How much to take

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

The recommended dose is:

Adults

The usual starting dose is 1 mg as a single morning dose or 0.5 mg twice daily. 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.

Patients with special risks

Your doctor will prescribe a lower dose if you have liver problems.

Use in children

Fluanxol is not recommended for children.

If you have the impression that the effect of this medicine is too strong or too weak, talk to your doctor, pharmacist or nurse.

How and when to take Fluanxol

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 older people) should be divided into a morning dose and an afternoon dose.

Duration of treatment

Patients often respond to this medicine 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 take more Fluanxol than you should

If you think that you or anyone else may have taken too many Fluanxol film-coated 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 this medicine has been given in overdose together with medicines known to affect the heart.

Symptomatic and supportive treatment will be initiated by your doctor/nurse.

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 tablet.

If you stop taking Fluanxol

Do not stop taking this medicine even if you begin to feel better, unless you are told to do so by your doctor.

If you stop taking this medicine too quickly, you may experience discontinuation symptoms. The most common symptoms are feeling sick (nausea), being sick (vomiting), anorexia, loose stools (diarrhoea), runny nose (rhinorrhoea), sweating, pains in the muscles (myalgias), feelings like pins and needles (paraesthesias), sleeplessness (insomnia), restlessness, anxiety and agitation. You may also experience dizziness (vertigo), alternate feelings of warmth and coldness, and shakiness (tremor). The symptoms usually begin within 1 to 4 days of stopping this medicine and go away within 7 to 14 days. If you get severe discontinuation symptoms, contact your doctor for advice.

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

4. Possible side effects

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

Side effects are most pronounced in the beginning of the treatment and most of them usually wear off during continued treatment:

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

Common (may affect up to 1 in 10 people)

- Racing heart (tachycardia), a sensation of a rapid, forceful, or irregular beating of the heart (palpitations).

Uncommon (may affect up to 1 in 100 people)

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

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

- Hypersensitivity, acute systemic and severe allergic reaction (anaphylactic reaction). Most anaphylactic reactions involve the skin with development of hives, generalized redness and swelling of face, eyelids, lips, tongue, throat, hands and feet. Other symptoms could be difficulty breathing, wheezing, chest tightness, rapid heart beat, dizziness and loss of consciousness. The symptoms of anaphylactic reaction can vary. In some people, the reaction begins very slowly, but in most the symptoms appear rapidly and abruptly.
- Low blood platelet count (thrombocytopenia), reduced white blood cell count (neutropenia, leukopenia), severe reduction in number of white blood cells which makes infections more likely (agranulocytosis).

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

- 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 have also been reported:

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

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

Common (may affect up to 1 in 10 people):

- 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 (may affect up to 1 in 100 people):

- 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 (may affect up to 1 in 1,000 people):

- High blood sugar (hyperglycaemia), abnormal glucose tolerance. Often there are no symptoms. Hyperglycaemia over a long time could result in fatigue, weight loss, excessive thirst and urination.
- Increased level of prolactin in the blood (hyperprolactinaemia). Symptoms of hyperprolactinaemia could be excessive milk production (galactorrhoea), lack of menstrual periods (amenorrhoea) and development of breasts in men (gynaecomastia).

As with other medicines that work in a way similar to flupentixol (the active ingredient of this medicine), 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 older people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Fluanxol

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

Do not use this medicine after the expiry date which is stated on the blister and label after EXP. The expiry date refers to the last day of that month. This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What Fluanxol contains

The active substance is flupentixol (as dihydrochloride).

Each Fluanxol film-coated tablet contains 0.5 mg or 1 mg flupentixol as hydrochloride salt.

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

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

What Fluanxol looks like and contents of the pack

Fluanxol is presented as 0.5 mg and 1 mg film-coated tablets.

Description of Fluanxol tablets:

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

The 1 mg film-coated tablets are oval, slightly biconvex, yellow, marked FF

Fluanxol film-coated tablets are available in blister packs of 60 tablets.

Marketing Authorisation Holder

Lundbeck Ltd.

Building K1 Timbold Drive,

Kents Hill,

Milton Keynes MK7 6BZ,

United Kingdom

Manufacturer:

H Lundbeck Ltd
Ottiliavej 9
DK-2500 Valby
Denmark.

Representative Office

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

Lundbeck (Ireland) Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24.

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