

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 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
- 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 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**
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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 antidepressants. These medicines act on nerve pathways in specific areas of the brain and help to correct certain chemical imbalances that are causing the symptoms of your illness.

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

2. What you need to know before you take Fluanxol

Do not take Fluanxol

- If you are allergic (hypersensitive) to flupentixol, other thioxanthene drugs or antipsychotic drugs or to any of the other ingredients of this medicine (listed in section 6).
- If you are feeling less alert than usual, or are drowsy or sleepy, or have serious problems with your blood circulation
- If you suffer with severe depression, which needs you to stay in hospital or if you need electroconvulsive therapy (ECT)
- If you suffer from periods of excitement, overactivity or mania.

Warnings and precautions

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

- have a heart condition (including an irregular heart beat) or severe breathing problems (such as asthma or bronchitis)

- have liver, kidney or thyroid problems
- suffer from epilepsy, or have been told that you are at risk of having fits (for example because of a brain injury or because of alcohol withdrawal)
- suffer from Parkinson's disease, or myasthenia gravis (a condition causing severe muscular weakness)
- have an enlarged prostate or suffer from a condition known as phaeochromocytoma (a rare type of cancer of a gland near the kidney)
- suffer from glaucoma (raised pressure within the eye)
- are diabetic
- 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 these patients.

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

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

- Antipsychotics or other medicines that change the heartbeat (quinidine, amiodarone, sotalol, dofetilide, erythromycin, moxifloxacin, cisapride, lithium)

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

- Tricyclic anti-depressants
- Barbiturates or other medicines that make you feel drowsy
- Anticoagulant drugs used to prevent blood clots (e.g. warfarin)
- Anticholinergic drugs (contained in some cold, allergy or travel sickness remedies as well as other medicines)
- Metoclopramide (used to treat nausea and other stomach conditions)

- Piperazine (used to treat worm infections)
- Levodopa or other medicines used to treat Parkinson's disease
- Sibutramine (used to reduce appetite)
- Digoxin (to control heart rhythm)
- Corticosteroids (e.g. prednisolone)
- Medicines used to lower the blood pressure such as hydralazine, alpha blockers (e.g. doxazosin) beta-blockers, methyldopa, clonidine or guanethidine
- Medicines used to treat epilepsy
- Medicines used to treat diabetes

Fluanxol can reduce the effect of adrenaline (epinephrine) and similar drugs.

Tell your doctor, dentist, surgeon or anaesthetist before any operation as Fluanxol can increase the effects of general anaesthetics, muscle relaxing drugs and drugs used to prevent clots.

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.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist 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 it is necessary.

The following symptoms may occur in newborn babies, of mothers that have used Fluanxol Tablets 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 your baby because small amounts of the medicine can pass into the breast milk.

Fertility

Flupentixol may decrease your sexual activity and fertility. These are not lasting effects. Please talk to your doctor about any problems.

Driving and using machines

There is a risk of feeling drowsy and dizzy when using Fluanxol especially at the start of your treatment. If this happens do not drive or use any tools or machines until you know you are not affected in this way.

Do not drive if you have blurred vision.

Fluanxol film-coated tablets contain sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

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

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

The dose varies and depends on the severity of the illness.

Adults

The starting dose is usually 1 mg daily taken as a single dose in the morning. This may be increased to 2 mg per day after one week. The maximum daily dose is 3 mg per day.

If you have liver problems, the level of flupentixol in your blood may be checked.

Older patients (above 65 years)

The starting dose is usually 0.5 mg daily taken as a single dose in the morning. This may be increased to 1 mg per day after one week. The maximum daily dose is 1.5 mg per day.

Use in children

Fluanxol is not recommended for children.

How and when to take Fluanxol

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

You may feel an improvement within two to three days.

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

Continue to take the tablets for as long as your doctor recommends. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

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
- Fits
- Low blood pressure, weak pulse, fast heart rate, pale skin, restlessness
- High or low body temperature
- Changes in the heart beat including irregular heart beat or slow heart rate

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 Fluanxol even if you begin to feel better, unless you have agreed this with your doctor.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Older patients tend to be more prone to some of these effects than younger patients and this may mean your treatment is supervised more closely.

Serious side effects

Stop taking Fluanxol and seek medical advice immediately if you have any of the following allergic reactions:

- Difficulty in breathing
- Swelling of the face, lips, tongue or throat which causes difficulty in swallowing or breathing
- Severe itching of the skin (with raised lumps)

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.

If you get any of the following symptoms you should contact your doctor immediately as your dose may need to be reduced or stopped:

- High fever, unusual stiffness of the muscles and changes in consciousness, especially if occurring with sweating and fast heart rate. These symptoms may be signs of a rare but serious condition called neuroleptic malignant syndrome that has been reported with the use of Fluanxol and similar medicines

- Unusual movements of the mouth and tongue as these may be early signs of a condition known as tardive dyskinesia
- Unusual muscle movements (such as circular movements of the eyes), stiffness, tremor and restlessness (for example difficulty in sitting or standing still) as these may be signs of a so-called “extra pyramidal” reaction
- Any yellowing of the skin and the white in the eyes (jaundice); your liver may be affected

Other side effects:

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

- Throbbing or fast heartbeats
- Reduction in blood platelets (which increases the risk of bleeding or bruising) and other blood cell changes
- Drowsiness
- Loss of co-ordination or altered muscle movements (including unusual movements of the mouth, tongue and eyeballs)
- Tremor
- Stiff or floppy muscles
- Dizziness
- Headache
- Poor concentration or confusion
- Rigidity of the whole body
- Speech problems
- Fits
- Blurred or abnormal vision
- Shortness of breath
- Dry mouth or increase in saliva
- Feeling sick or vomiting
- Indigestion or stomach pain
- Flatulence (wind), constipation or diarrhoea
- Abnormal urination (such as decrease in the frequency or amount)
- Increased sweating or greasy skin
- Itching, rashes or skin reactions (including sensitivity to sunlight)
- Muscle pain
- Raised blood levels of glucose or the hormone prolactin
- Loss of control of blood sugar levels
- Changes in appetite or weight
- Low blood pressure
- Hot flushes
- General weakness or pain, tiredness or feeling unwell
- Abnormal liver function tests
- Unexpected excretion of breast milk
- Insomnia
- Depression
- Nervousness or agitation
- Reduction in your sex drive
- Men may experience breast enlargement or problems with ejaculation or erections
- Women may experience an absence of menstrual periods

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

- Slow heartbeat and abnormal ECG heart tracing.
- Life threatening irregular heart beats.

In rare cases irregular heart beats (arrhythmias) may have resulted in sudden death.

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 (see details below).

By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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 that is printed on the label. The expiry date refers to the last day of that month
- This medicinal product 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 to protect the environment.

6. Contents of the pack and other information

What Fluanxol contains

The active substance is flupentixol (as dihydrochloride).

Each film-coated tablet contains 0.5 mg or 1 mg flupentixol.

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

Coating and colour: macrogol 6000, polyvinyl alcohol, macrogol 3350, talc, iron oxide yellow (E172) and titanium dioxide (E171).

What Fluanxol looks like and contents of the packs

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

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

They are available in blister packs of 60 tablets.

Marketing Authorisation Holder

For any information about this medicine, please contact the Marketing Authorisation holder:

Lundbeck Limited

Iveco House,

Station Road,

Watford,

Hertfordshire,

WD17 1ET,

United Kingdom

Manufacturer

H. Lundbeck A/S

Ottiliavej 9

DK-2500 Valby

Denmark

This leaflet was last revised in 01/2021

To request a copy of this leaflet in braille, large print or audio please call free of charge:

0800 198 5000

Please be ready to give the following information:

| Product name | Product code number |
|-------------------------------------|----------------------------|
| Fluanxol 0.5 mg film-coated tablets | PL 00458/0011R |
| Fluanxol 1 mg film-coated tablets | PL 00458/0037 |

This is a service provided by the Royal National Institute of Blind People.