

Fluanxol[®] (flu-ANK-sol)

Fluanxol[®] Depot 20 mg/mL

Fluanxol[®] Concentrated Depot 100 mg/mL

Flupenthixol decanoate (flu-PEN-thic-sol deck-can-OH-ate)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet contains answers to some common questions about Fluanxol.

It does not contain all the information that is known about Fluanxol. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Fluanxol is used for

Fluanxol is used for the long-term treatment of schizophrenia, a mental illness with disturbances in thinking, emotional reactions and behaviour, and other chronic mental conditions.

Fluanxol belongs to a group of medicines called thioxanthene neuroleptics. It helps to correct chemical imbalances in the brain, which may cause mental illness.

Your doctor, however, may prescribe it for another purpose.

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

This medicine is only available with a doctor's prescription.

Fluanxol is not addictive.

Before you are given it

When you must not be given it

Do not use Fluanxol if you are allergic to it, to any other similar medicines (such as thioxanthenes or phenothiazines), or the ingredient fractionated coconut oil.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

Do not use Fluanxol if you have:

- diminished consciousness due to any cause
- collapse due to very low blood pressure
- brain damage
- diseases of the blood with a reduced number of red or white blood cells or platelets
- phaeochromocytoma, a rare tumour of the adrenal gland which sits near the kidney.

Do not give Fluanxol to anyone who currently has alcohol poisoning, or poisoning with

medicines used to produce calmness or to help you sleep, or medicines used to treat epilepsy or strong pain.

Do not give Fluanxol to anyone who is unconscious or in a coma.

Do not give Fluanxol to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Do not give Fluanxol to patients with mental illness who are highly distressed, or elderly patients who are confused and/or distressed.

Do not use it after the expiry date printed on the pack.

If you use it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

Do not use it if the packaging is torn or shows signs of tampering.

Before you are given it

Tell your doctor if:

- 1. you have allergies to any other substances such as foods, preservatives or dyes.**
- 2. you are pregnant or intend to become pregnant.**

Like most medicines of this kind, Fluanxol is not recommended for use during pregnancy unless clearly necessary. The general condition of your baby might be affected by the use of this medicine.

The following symptoms may occur in newborn babies of mothers who have used Fluanxol in the 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 should contact your doctor.

3. you are breast-feeding or planning to breast-feed.

It is not recommended that you breast-feed while using Fluanxol. Its active ingredient passes into breast milk and therefore there is a possibility that your baby might be affected.

4. you have, or have had, the following medical conditions:

- arteriosclerosis, a disease affecting the arteries
- convulsions, fits or seizures
- decreased blood supply to the brain
- diabetes, a disorder of metabolism in which the amount of sugar in the blood is too high
- glaucoma, a condition in which there is usually a build-up of pressure in the eye
- heart and blood vessel problems
- kidney problems
- liver problems
- low potassium and/or low magnesium levels in the blood
- organic brain syndrome
- parkinsonism, a disease of the brain affecting movement
- risk factors for stroke
- tardive dyskinesia, a reaction to some medicines with worm-like movements of the tongue, or other uncontrolled movements of the mouth, tongue, cheeks or jaw which may progress to the arms and legs.
- If you or someone else in your family has a history of blood clots, as medicines like these

have been associated with formation of blood clots

Also tell your doctor if you will be in a hot environment or you do a lot of vigorous exercise.

Fluanxol may make you sweat less, causing your body to overheat.

Tell your doctor if you are exposed to pesticides that contain phosphorus.

The risk of you experiencing a side effect may be increased.

If you have not told your doctor about any of the above, tell them before you are given Fluanxol.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Fluanxol may interfere with each other. These include:

- tricyclic antidepressants, monoamine oxidase (MAO) inhibitors and lithium, medicines used to treat depression or mood swings
- phenobarbitone and carbamazepine, medicines used to treat convulsions and epilepsy
- medicines used to treat strong pain
- medicines used to produce calmness or to help you sleep
- medicines used to treat high blood pressure (hypertension), including debrisoquine, guanethidine and clonidine
- levodopa, a medicine used to treat Parkinson's disease
- medicines which stimulate the body, getting it ready for action, such as adrenaline
- metoclopramide, a medicine used to relieve nausea and vomiting
- piperazine, a medicine used to treat worm infections
- medicines used to treat changes in the rhythm or rate of the heart

beat, e.g. quinidine, amiodarone, sotalol and dofetilide

- antipsychotics, a class of medicines used to treat certain mental and emotional conditions, e.g. thioridazine
- certain medicines used to treat infections, such as erythromycin, gatifloxacin and moxifloxacin
- medicines used to relieve the symptoms of allergy, including terfenadine and astemizole
- cisapride, used to treat stomach problems
- thiazide diuretics, also called fluid or water tablets
- medicines used to relieve stomach cramps or spasms, to prevent travel sickness and to treat Parkinson's disease, such as atropine or related medicines.

These medicines may be affected by Fluanxol, or may affect how well it works. You may need to use different amounts of your medicines, or take different medicines. Your doctor will advise you.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while using Fluanxol.

How it is given

How much is given

Your doctor will decide what dose you will receive. This depends on your condition and other factors, such as your weight and your response to the medicine.

Fluanxol Depot

Generally, the starting dose is 20 to 40 mg (1 to 2 mL). A second dose of 20 to 40 mg (1 to 2 mL) is usually given 4 - 10 days after the first injection, and further doses are given every 2 to 4 weeks for the majority of patients.

Fluanxol Concentrated Depot

Patients who require higher doses and/or who have problems with larger

injection volumes may be given Fluanxol Concentrated Depot.

Your doctor may have prescribed a different dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you. Follow the instructions they give you.

They will tell you exactly how much you will be given.

How it is given

Fluanxol is given as an injection into a large muscle where it is slowly released over time. The injection should only be given by a doctor, nurse or other trained person.

How often it is given

It is recommended that Fluanxol is given every 2 – 4 weeks, depending on how your body responds to the medicine.

How many injections you will need

Continue having your injections for as long as your doctor tells you to.

Fluanxol helps control your condition, but does not cure it.

Therefore, you will need regular injections.

If you forget to have an injection

If you forget to keep an appointment, contact your doctor as soon as you remember, so that you can make another one.

Overdose

As Fluanxol is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience any side effects after being given Fluanxol, immediately telephone your doctor, or the Poisons

Information Centre (Tel: 13 11 26 for Australia and Tel: 0800 764 766 for New Zealand), or go to Accident and Emergency at your nearest hospital.

You may need urgent medical attention.

Symptoms of an overdose may include sleepiness, coma, extreme agitation, excitement, confusion, convulsions and extremely high or low body temperature.

Uncontrollable movements may develop, and collapse due to very low blood pressure or difficulty breathing may occur. Changes in the rhythm or rate of the heart beat have been seen in Fluanxol overdose when medicines known to affect the heart have also been taken.

While you are using it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Fluanxol.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you become pregnant while using Fluanxol, tell your doctor immediately.

Tell your doctor immediately if you notice any worm-like movements of the tongue, or other uncontrolled movements of the tongue, mouth, cheeks or jaw which may progress to the arms and legs.

These are symptoms of a condition called tardive dyskinesia, which may develop in people taking similar medicines, including Fluanxol.

This condition is more likely to occur during long-term treatment with Fluanxol, especially in elderly women. In very rare cases, this may be permanent. However, if detected early, these symptoms are usually reversible.

Also tell your doctor if you notice any soreness of the mouth, gums, throat or other flu-like symptoms.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

Fluanxol may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some blood and liver tests from time to time, particularly during the first months of therapy, to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not take any medicines that cause drowsiness while you are using Fluanxol, unless recommended by your doctor.

Do not miss any injections, even if you feel better.

Fluanxol helps control your condition, but does not cure it. Therefore, you will need regular injections.

Do not stop using Fluanxol suddenly.

If Fluanxol is stopped suddenly, you may experience symptoms such as nausea, vomiting, loss of appetite, diarrhoea, runny nose, sweating, aching muscles, pins and needles, sleeplessness, restlessness, anxiety, or agitation.

Your doctor may want to gradually reduce the amount you are given before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Fluanxol affects you.

It may cause drowsiness, tiredness, sleepiness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Be careful when drinking alcohol while you are using this medicine.

If you drink alcohol, drowsiness or sleepiness may be worse.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.

Standing up slowly will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Fluanxol.

It helps most people with mental illness, but it may have unwanted side effects in a few people.

If you are over 65 years of age you may have an increased chance of getting side effects.

Tell your doctor if you notice any of the following and they worry you:

- restlessness
- difficulty sleeping
- involuntary muscle contractions
- headache
- drowsiness
- tiredness, sleepiness
- dry mouth
- constipation

- increased salivation or increased sweating
- nausea
- weight changes
- impaired sexual function
- change in your menstrual periods
- skin rash
- hair loss
- pain at the place where your injection is given.

Tell your doctor immediately if you notice any of the following:

- sudden onset of unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, or shuffling walk and stiffness of the arms and legs
- worm-like movements of the tongue or other uncontrolled movements of the mouth, tongue, cheeks or jaws, which may progress to the arms and legs
- difficulty swallowing
- mood changes
- blurred vision or difficulty focusing
- difficulty passing urine
- changes in heart rate and blood pressure
- fainting
- high pressure in the eye
- breast enlargement in men
- unusual secretion of breast milk
- yellowing of the skin and/or eyes, also called jaundice
- tiredness, headaches, dizziness, being short of breath when exercising and looking pale
- frequent infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal, nosebleeds
- swelling of the gums
- severe pain in the stomach with bloating, gut cramps and vomiting.
- 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.

These may be serious side effects of Fluanxol. You may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- serious allergic reaction (symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives)
- convulsions
- sudden increase in body temperature, extremely high blood pressure and severe convulsions.

These are very serious side effects.

You may need urgent medical attention or hospitalisation.

These side effects are generally rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using it

Storage

Keep Fluanxol in the pack until it is time to use it.

If you take the ampoules out of the box they may not keep well.

Keep Fluanxol away from sunlight.

Keep the medicine in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.
Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor stops giving you this medicine, or the expiry date has passed, ask your pharmacist what to do with any that is left over.

Return any unused medicine to your pharmacist.

Product description

What it looks like

Fluanxol comes in two types of injections:

- Fluanxol Depot 20 mg/mL solution for injection - clear, colourless to slightly yellowish oil
- Fluanxol Concentrated Depot 100 mg/mL concentrated injection - clear, yellow to yellowish oil.

A box contains 5 ampoules.

Ingredients

Active ingredient(s):

- Fluanxol 20 mg/mL injection - 20 mg flupenthixol decanoate per 1 mL or 40 mg flupenthixol decanoate per 2 mL
- Fluanxol 100 mg/mL injection - 100 mg flupenthixol decanoate per 1 mL.

Inactive ingredient:

- coconut oil - fractionated.

Manufacturer/Sponsor

Fluanxol is made by H. Lundbeck A/S, Denmark.

Distributed in Australia by:

Lundbeck Australia Pty Ltd
1 Innovation Rd
North Ryde NSW 2113
Ph: +61 2 8669 1000

Distributed in New Zealand by:

Healthcare Logistics
PO Box 62027
Mt Wellington, Auckland
Ph: +64 9 9185100

This leaflet was prepared on 13 December 2011.

Australian Registration Numbers:

Fluanxol Depot

20 mg/mL AUST R 47109
40 mg/2mL AUST R 47247

Fluanxol Concentrated Depot

100 mg/mL AUST R 47107

“Fluanxol” is the registered trademark of H. Lundbeck A/S.