

PART III: CONSUMER INFORMATION

PrFLUANXOL®
Flupentixol Tablets
(as flupentixol dihydrochloride)

PrFLUANXOL® DEPOT
Flupentixol Decanoate Intramuscular Injection

This leaflet is part III of a three-part "Product Monograph" published when PrFluanxol®, and PrFluanxol® Depot were approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about Fluanxol. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information leaflet carefully before you start your medicine, even if you have taken this drug before. Keep this leaflet handy in order to consult it while taking your medication.

Fluanxol has been prescribed only for you. Do not give it to anybody else.

ABOUT THIS MEDICATION

What the medication is used for:

Fluanxol is a prescription medicine that belongs to a family of medicines used to treat schizophrenia.

You may be given Fluanxol in the form of tablets or by injection. Depending on the circumstances, your doctor will decide which form of Fluanxol is right for you.

Fluanxol tablets need to be taken **every day** to be effective.

If you receive Fluanxol by injection, it will be administered by a doctor or nurse. Fluanxol by injection is effective when administered as infrequently as once every **2-3** weeks.

What it does:

Fluanxol belongs to a group of medicines known as antipsychotics (also called neuroleptics). 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.

When it should not be used:

- If you are allergic to any of its ingredients (see the What the nonmedicinal ingredients are), or to thioxanthenes or other phenothiazine types of medications
- If you suffer from impaired consciousness due to the influence of alcohol or drugs such as barbiturates and opiates, or as a result of brain damage, shock (circulatory collapse), or being in a comatose state
- If you have liver disease, kidney disease, severe heart problems or severe blockage of some arteries

What the medicinal ingredient is:

Each Fluanxol Tablet contains flupentixol dihydrochloride. Fluanxol Depot injection contains flupentixol decanoate.

What the nonmedicinal ingredients are:

Fluanxol tablets:

Betadex, croscarmellose sodium, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, ~~po~~ maize starch, talc, yellow iron oxide, sunset yellow FCF (FC&C yellow #6 aluminum lake), vegetable oil, water

Fluanxol Depot:

vegetable oil (medium-chain triglycerides)

What dosage forms it comes in:

Fluanxol is available as a tablet and as an injection.

Tablets: The 0.5 mg tablet is yellow in colour and the 3 and 5 mg tablets are light yellow brown in colour.

Injection: PrFluanxol® Depot is available in two strengths: a 2% solution and a 10% solution.

WARNINGS AND PRECAUTIONS

Serious Warnings and Precautions

Neuroleptic malignant syndrome (NMS) is a rare, but life-threatening, disorder of the nervous system that has been linked with drugs such as Fluanxol. It is characterized by high fever, unusual stiffness of the muscles, disorder of your consciousness, sweating and fast heart rate.

BEFORE you use Fluanxol talk to your doctor or pharmacist if:

- you have used Fluanxol or any other treatment for schizophrenia before and if you had any problems
- you are taking any other prescription or non-prescription medicines
- you are pregnant or thinking of becoming pregnant, or if you are breast-feeding;
- you regularly drink a lot of alcohol
- you have Parkinson's disease or have ever had seizures
- you have dementia
- you have glaucoma
- you have, or have ever had irregular heart rhythms
- you or someone in your family has a history of blood clots
- you have risk factors for stroke (e.g. smoking, high blood pressure)
- you have hypokalemia or hypomagnesia (too little potassium or magnesium in your blood)
- you have a history of cardiovascular disorders
- you use other antipsychotic medicine
- you are more excited or overactive than normal, since Fluanxol may increase these feelings

- you need surgery; be sure to tell every doctor you consult that you are taking Fluanxol
- you are being treated for cancer (applies to Fluanxol Depot only)

It is important that you tell your doctor about all your past and present medical conditions.

Effects on Newborns:

In some cases, babies born to a mother taking Fluanxol during pregnancy have experienced symptoms that are severe and require the newborn to be hospitalized. Sometimes, the symptoms may resolve on their own. Be prepared to seek immediate emergency medical attention for your newborn if they have difficulty breathing, are overly sleepy, have muscle stiffness, or floppy muscles (like a rag doll), are shaking, or are having difficulty feeding.

Effects on Fertility:

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

very important to keep your scheduled appointments for the injections.

Overdose:

Symptoms of overdose with Fluanxol may include:

- drowsiness
- unconsciousness
- muscle movement 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.

Fluanxol tablets: Contact your doctor or nearest hospital emergency department as soon as you realize you have taken too much Fluanxol, even if you do not feel sick.

Fluanxol injection: Fluanxol injection is given by a doctor or nurse. Any overdose should be managed by a doctor or nurse experienced in the use of intramuscular injections.

Missed dose:

Fluanxol Tablets: If you miss a dose, take it as soon as you remember, as long as it is more than 6 hours before the next dose is due. If it is less than 6 hours before the next dose is due, just take your next regularly scheduled dose and try not to miss any more. Do not try to make up for a missed dose by doubling up on the next dose.

Fluanxol Injection: Fluanxol injection is given by a doctor or nurse. If you miss an appointment for an injection, contact your doctor as soon as possible in order to schedule a new appointment. Any missed dose should be managed by a doctor or nurse experienced in the use of intramuscular injections.

INTERACTIONS WITH THIS MEDICATION

Drugs that may interact with Fluanxol include:

- tricyclic antidepressant medicines
- guanethidine and similar medicines (used to lower the blood pressure)
- barbiturates and similar medicines
- levodopa and similar medicines (used to treat Parkinson's disease)
- metoclopramide (used in the treatment of gastro-intestinal disorders)
- other antipsychotic medicines (e.g. thioridazine)
- medicines that change the heartbeat (e.g. quinidine, amiodarone, sotalol, erythromycin, moxifloxacin, lithium)

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

Consult your doctor before taking other medications, including over-the-counter medicines and herbal remedies. Some drugs can produce additional side-effects when they are used in combination with Fluanxol.

PROPER USE OF THIS MEDICATION

Usual dose:

Fluanxol Tablets: It is very important that you take Fluanxol tablets exactly as your doctor instructs you. Never increase or decrease the amount of Fluanxol tablets you are taking unless your doctor tells you to. Do not stop taking Fluanxol even if you begin to feel better, unless you are told to do so by your doctor. Fluanxol tablets may be taken with or without food.

Fluanxol Injection: If you are prescribed Fluanxol by intramuscular injection, it will be given by a doctor or nurse. It is

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medications Fluanxol can cause some side effects. You may not experience any of them. For most patients these side effects are likely to be minor and temporary. However, some may be serious. Consult your doctor if you experience these or other side effects.

At the beginning of treatment, Fluanxol may make you feel drowsy and dizzy, so you should not drive a car or use any tools or machines until you are sure Fluanxol does not affect your mental alertness.

Side-effects that have been reported by patients taking Fluanxol include:

- an allergic reaction (symptoms include skin rash, hives, swelling, difficulty breathing).
- if you experience fever (increased temperature) or soreness of the mouth, gums, or throat that happens while you are taking

Fluanxol, contact your doctor **immediately**.

- muscle spasm, stiffness, shaking or uncontrolled body movements; this may indicate that you have a syndrome called Tardive Dyskinesia. These can happen in different parts of the body, such as the tongue, face, mouth, jaw, eyes, hands, arms and legs. Small uncontrollable movements of the tongue may be an early sign of the syndrome. If Fluanxol is stopped when these symptoms are noticed, the syndrome may not develop further. Tardive Dyskinesia can sometimes be permanent, even if you stop taking Fluanxol. Contact your doctor immediately if this happens to you.
- dry mouth, dizziness, blurred or altered vision, constipation, excessive salivation or sweating, trouble passing urine, decreases in blood pressure, increases in heart rate, weight changes, skin rash, decreased sexual interest or function, and changes in your monthly cycle (if you are female). Tell your doctor or pharmacist if you think you have any of these or other effects while taking Fluanxol.
- a serious condition called Neuroleptic Malignant Syndrome; symptoms include fever, stiff muscles, confusion, reduced consciousness, irregular heart rate and sweating. Go to the nearest Emergency Room of a hospital if you think this is happening to you.
- 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.

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 rate and changes to the ECG)
- Ventricular arrhythmias (irregular heart beat)
- Torsades de Pointes (a special kind of irregular heart beat)

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

Your doctor should check your body weight before starting Fluanxol and continue to monitor it for as long as you are being treated.

Your doctor should take blood tests before starting Fluanxol. They will monitor blood sugar, and the number of infection fighting white blood cells. Your doctor should continue to monitor your blood for as long as you are being treated.

If you have high levels of prolactin (measured with a blood test) and a condition called hypogonadism, you may be at increased risk of breaking a bone due to osteoporosis. This occurs in both men and women.

You should also tell you doctor if you notice any symptoms that worry you, even if you think the problems are not connected with Fluanxol or are not listed here.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and seek immediate emergency assistance
		Only if severe	In all cases	
Common	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), increased muscle stiffness (hypertonía)	✓		
Uncommon	Unusual movements of the mouth and tongue		✓	
	Yellowing of the skin and the white in the eyes and extremities.		✓	
	High fever, unusual stiffness of the muscles and disorder of your consciousness, especially if occurring with sweating and fast heart rate			✓
	Circular movement of the eye (oculogyration)		✓	
	Convulsion			✓
	Long-lasting (greater than 4 hours in duration) and painful erection of the penis			✓
	New or worsening constipation		✓	

This is not a complete list of side effects. For any unexpected effects while taking Fluanxol, contact your doctor or

pharmacist.

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HOW TO STORE IT

Keep Fluanxol out of the reach of children.

Safely discard any unused Fluanxol, or any Fluanxol that has passed the expiry date on the label.

Medicines should not be disposed of via wastewater or household waste, ask your pharmacist how to dispose of medicines no longer required, these measures will help protect the environment.

Fluanxol tablets: keep in a safe place between 15°C and 25°C in a well-closed container

Fluanxol injection: ampoules should be kept in a safe place between 15°C and 25°C, protected from light.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at:
www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to:
Canada Vigilance Program
Health Canada
Postal Locator 0701C
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

For questions or concerns and to find the full product monograph prepared for healthcare professionals, go to <http://www.lundbeck.ca> or contact the sponsor, Lundbeck Canada Inc. at 1-800-586-2325.