

Prolixin (fluphenazine)

Warnings

Tardive Dyskinesia (TD)

Fluphenazine may cause tardive dyskinesia (TD), a potentially permanent side effect of antipsychotic medications. TD is characterized by movements you may be unable to control such as grimacing, smacking of lips, tongue darting or rolling and movements of the extremities. Sometimes you may not notice that you are doing these movements. TD usually begins after several months of treatment and may be irreversible. However, if TD is caught early, it may be reversible. If you develop these symptoms, call your healthcare provider immediately.

Neuroleptic Malignant Syndrome (NMS)

Neuroleptic malignant syndrome “NMS” is a rare, life-threatening, neurological disorder most often caused by an adverse reaction to antipsychotic medications. Symptoms of “NMS” include sudden high fever, sweating, changing blood pressure, dizziness, fatigue, muscle stiffness, as well as changes in liver & kidney function. In most cases, the disorder develops within the first 2 weeks of medication treatment. Early identification of and treatment for individuals with neuroleptic malignant syndrome slows the progression and improves recovery from “NMS”. A different antipsychotic can be reintroduced very slowly once recovery is complete, although there is a risk that the syndrome might recur. Notify your healthcare provider immediately if you suspect you are developing “NMS”.

Brand/Generic Names

Novartis manufactures and markets fluphenazine under the brand name Prolixin[®]. Generic forms of fluphenazine are marketed by Apothecan, Novex Pharma, and Bedford Laboratories.

- Brand Name: Prolixin

Available forms...

- Prolixin[®] /Fluphenazine HCL tablets

1 mg, 2.5 mg, 5 mg, and 10 mg

- Prolixin[®] /Fluphenazine HCL Elixir

0.5 mg/ml (2.5mg / 5ml teaspoon) 60 ml and 473 ml bottles

5 mg/ml (concentrate) 60 ml and 473 ml bottles

- Prolixin[®] /Fluphenazine HCL injection (short acting injection)

2.5mg/ml 5 ml vial

- Prolixin[®] /Fluphenazine Decanoate (long acting injection)

25mg/ml Multidose 5ml vial and single dose 1ml vial

- Generic name: fluphenazine pronounced: *floo fen' a zeen*

What is Prolixin[®]/ Fluphenazine and what does it treat?

Prolixin[®] is a phenothiazine antipsychotic agent that was developed in the 1960s. It is indicated for the treatment of schizophrenia and is useful for treating positive symptoms such as hallucinations, delusions, bizarre behavior and hostility. Prolixin[®] is commonly used as the long acting injection (Depot) form in patients who tolerate an intramuscular injection better than taking oral medications. The Depot injection can last up to 2 to 4 weeks before the next injection is needed. Like most antipsychotic agents, Prolixin[®] is effective for about 60 percent of those who try it.

What is the most important information I should know about Prolixin?

- If you are taking oral fluphenazine, do not stop taking this medication or change your dose without first talking with your health care provider.
- You should not use illegal drugs or drink alcohol while taking Prolixin[®] because the benefits of your medication will go away and you could experience more drowsiness and muscle side effects.
- Fluphenazine may increase the chances of having: muscle tremors, muscle stiffness and/or abnormal muscle twitching that may affect any muscle and may be irreversible. Alert your doctor if any of these signs develop.

What should I discuss with my healthcare provider before taking Prolixin®?

- Which symptoms of your condition or illness are most bothersome to you.
- The medications you have taken in the past for psychotic symptoms (hallucinations, disturbing thoughts, disorganized behavior or speech, fear that others are planning to hurt you). It would be helpful for your provider to know which medications were effective and which were not.
- If you had any serious side effects to other antipsychotic medications like dystonia (muscle cramps/stiffness), tardive dyskinesia (involuntary muscle movements), neuroleptic malignant syndrome, weight gain, or diabetes, tell your healthcare provider.
- If you have ever had seizures.
- All other medications you are currently taking.
- If you smoke cigarettes, use illegal drugs, or drink alcohol.
- About any medication allergies you have.
- If you are pregnant, plan to get pregnant, or are breast feeding.
- Tell your doctor if you have thoughts of suicide.

How should I take Prolixin®?

Prolixin® comes as a tablet or oral liquid (elixir and concentrate) to take by mouth. It can be taken one to three times a day and may be taken with or without food. Follow the directions on your prescription label carefully, and ask your health care provider to explain any part you do not understand. Take this medication exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor.

Prolixin® oral liquid comes with a specially marked dropper for measuring the dose. Ask your pharmacist to show you how to use the dropper. Do not allow the liquid to touch your skin or clothing; it can cause skin irritation. Dilute the concentrate in water, lemon-lime soda, carbonated orange beverage, milk, or V-8, pineapple, apricot, prune, orange, tomato, or grapefruit juice just before taking it. Do not use beverages containing caffeine (coffee, tea, and cola) or apple juice.

If you are receiving Prolixin® Depot muscular injections you need to return every 2 – 4 weeks depending on your administration schedule. Please inform your doctor if you experience any pain, redness or irritation in or around the site of injection.

Continue to take Prolixin® even if you feel well. Do not stop taking Prolixin® without talking to your doctor, especially if you have taken large doses for a long time. If your doctor recommends discontinuation of Prolixin® therapy, it is usually best to decrease your dose gradually. This drug must be taken regularly for a several weeks before its full effect is felt. Some patients may take this medicine lifelong.

What happens if I miss a dose of Prolixin®?

If a dose of Prolixin® is missed, take it as soon as you remember to, if it is not too close to when your next dose is due. Do not double up on your next dose.

What should I avoid while taking Prolixin®?

- Please check with your healthcare provider before taking any other prescription, non-prescription, or herbal/nutritional supplements.
- Avoid smoking cigarettes, using illegal drugs, or drinking alcohol.
- Some people get drowsy on Prolixin®, avoid driving a car until you are sure how the medication will affect you.

What happens if I overdose with Prolixin®?

- If you overdose with Prolixin you may experience slowed or very stiff muscle movements, sleepiness, and possible loss of consciousness, heart palpitations and/or seizures.
- Do not try to self-induce vomiting because of the risk of choking or damaging the lungs.
- Go to your nearest emergency room and report what happened.

What are the possible side effects of Prolixin ®?

Common adverse effects of Prolixin® usually include sleepiness, dizziness, constipation, excessive saliva in mouth, and weight gain. An adverse effect that may occur is known as orthostatic hypotension (dizziness due to a lowering of your blood pressure when you sit up or stand up). Occasionally this can lead to fainting and falling down, therefore, people taking Prolixin® should be careful when they change positions. These adverse effects are usually mild and usually go away after the first several days of starting treatment or increasing a dose.

Prolixin® has (30-40%) incidence of extrapyramidal symptoms such as muscle spasms, cramps, or posturing movements, and side effects such as restlessness, muscle rigidity, and tremor.

Are there any risks for taking Polixin for long periods of time?

Prolixin® may cause tardive dyskinesia (see warnings above). TD is characterized by involuntary movements such as grimacing, sucking/smacking of lips, and spasmodic movements of the extremities. It usually begins after several months of treatment and may be irreversible. Same comment as above

If you experience any of the following symptoms, call your health care provider immediately:

- jaw, neck, and back muscle spasms
- slow or difficult speech
- shuffling walk
- persistent fine tremor or inability to sit still
- fever, chills, sore throat, or flu-like symptoms
- difficulty breathing or swallowing
- severe skin rash
- yellowing of the skin or eyes
- irregular heartbeat

What other drugs interact with Prolixin®?

There are many other medications that may interact with Prolixin®. Any other medication that causes sleepiness may increase the same side effects of Prolixin® and increase your chances of unsteadiness and falling. Others include: opioid analgesics, alcohol, antihistamines and tricyclic antidepressants.

- Medications that may increase levels of Prolixin® in your body: miconazole, paroxetine (Paxil®), , fluoxetine (Prozac®), quinidine, ropinirole (Requip®), lopinavir/ritonavir (Kaletra®), ritonavir (Norvir®)
- Medications that may decrease levels of Prolixin in your body: carbamazepine (Tegretol®), oxcarbazepine (Trileptal®), phenytoin (Dilantin), rifampin (Rifadin).

How long does it take for Prolixin®to work?

A patient should continue a trial of Prolixin® for at least four to six weeks. Some symptoms such as hallucinations, anxiety, paranoia, and bizarre behavior may start to improve within 1 – 2 weeks; however, it is important to continue treatment to observe the maximum beneficial effects.

*Updated by Mark E. Schneiderhan, PharmD
March 2007*



NAMI wishes to thank the College of Psychiatric and Neurological Pharmacists for producing this fact sheet.