



Prolixin/Prolixin Decanoate (fluphenazine)

Generic names: Fluphenazine and fluphenazine decanoate

Available strengths: 1 mg, 2.5 mg, 5 mg, 10 mg tablets;

2.5 mg/mL, 5 mg/mL oral solution;

2.5 mg/mL injection; 25 mg/mL injection (Prolixin Decanoate)

Available in generic: Yes

Drug class: First-generation (conventional) antipsychotic

General Information

Prolixin (fluphenazine) belongs to a class of antipsychotics known as the **first-generation antipsychotics**, sometimes referred to as *conventional* or *typical* antipsychotics. The first-generation antipsychotics represent an older class of antipsychotics that have been the standard for treating psychotic disorders for many decades. When compared with a newer class of **second-generation antipsychotics**, these earlier antipsychotics are referred to as *typical* or *conventional* because they lack the wider spectrum of therapeutic activity. The first-generation antipsychotics are also more likely to induce side effects that cause movement disorders, such as **extrapyramidal symptoms (EPS)** and **tardive dyskinesia (TD)**, than the newer antipsychotics.

Prolixin is a relatively high-potency agent, compared with other first-generation antipsychotics such as Thorazine (chlorpromazine) and Mellaril (thioridazine). The high-potency antipsychotics are less sedating and have fewer **anticholinergic side effects**, but they frequently cause EPS.

Prolixin was approved by the U.S. Food and Drug Administration for treatment of psychotic disorders, including schizophrenia, schizoaffective disorder, and drug-induced psychosis. The use of a drug for its approved indications is called its *labeled use*. In clinical practice, however, physicians often prescribe drugs for *unlabeled* (“off-label”) uses when published clinical studies, case reports, or their own clinical experiences support the efficacy and safety of the medications for these uses. For instance, Prolixin may be prescribed with a mood stabilizer to treat acute mania, since the mood stabilizer has a slower onset of action. After the symptoms of mania abate, Prolixin is discontinued and the mood stabilizer is continued alone.

Prolixin is available in generic form in all preparations from various generic manufacturers. Prolixin also comes in a long-acting preparation, **Prolixin Decanoate** (fluphenazine decanoate), for intramuscular injection. Given by deep intramuscular injection, the drug is deposited into muscle tissues and is absorbed slowly into circulation from its depot site. For patients who may have difficulty taking their medication as scheduled,

Prolixin Decanoate offers the convenience of an injectable form that can be given every 2–3 weeks without the need of oral medication.

Dosing Information

The recommended starting oral dosage for Prolixin in treating schizophrenia is 2–5 mg/day, taken in divided doses twice daily. It may be taken without regard to meals. The dosage may be increased weekly in increments of 2.5 mg/day. The dosage usually ranges between 5 mg/day and 10 mg/day but should not exceed 20 mg/day. Dosages above 20 mg/day may be needed for some patients but may be associated with more frequent EPS.

Prolixin Decanoate is administered by deep intramuscular injection. Patients' symptoms should be stabilized while they are taking oral Prolixin before switching to the decanoate injection. The initial dosage of Prolixin Decanoate should not exceed 50 mg, and the patient may need to continue taking oral Prolixin until the effective decanoate dosage is established. The usual maintenance dosage for Prolixin Decanoate is in the range of 25–50 mg every 2–3 weeks.

Common Side Effects

Prolixin is less sedating than the low-potency, conventional antipsychotics, but it often induces bothersome side effects called **extrapyramidal symptoms**. These are neurological disturbances caused by antipsychotics (or a neurological disorder) in the area of the brain that controls motor coordination. When disruption occurs in a particular area of the brain, it can produce symptoms that mimic Parkinson's disease (**parkinsonism**), including muscle stiffness, rigidity, tremor, drooling, and a “mask-like” facial expression. However, unlike Parkinson's disease, which is a progressive neurological disease, parkinsonism from treatment with an antipsychotic is reversible. The Parkinson-like symptoms may be treated, and prevented, by using antiparkinson agents (also called anticholinergic agents) such as Cogentin (benztropine), Benadryl (diphenhydramine), Artane (trihexyphenidyl), and Kemadrin (procyclidine).

Akathisia is another form of EPS characterized by a subjective sense of restlessness accompanied by fidgeting, inability to sit still, nervousness, muscle discomfort, and agitation. Generally, antiparkinson agents are not effective in managing akathisia. Use of Inderal (propranolol), a *beta-blocker*, may be helpful and is sometimes prescribed by physicians.

Dystonia is a type of EPS with acute onset. The patient may develop a sudden spasm of the muscles of the tongue, jaw, and neck. **This is not an allergic reaction to the antipsychotic medication.** Although a dystonic reaction may be painful and frightening, it can be rapidly reversed with an intramuscular injection of an anticholinergic medication such as Cogentin or Benadryl. With a dystonic reaction, the patient should seek immediate medical attention and receive treatment.

Elevation of **prolactin levels** is common with conventional antipsychotics. Prolactin is a hormone produced in the area of the brain called the pituitary gland. It is normally elevated in women following childbirth, stimulating lactation, or milk production. The effects of elevated prolactin include breast enlargement and milk production (**galactorrhea**) in both women and men. Elevated prolactin is associated with impotence in men and irregular menstrual cycles or absence of menstruation in women. When side effects from elevated prolactin levels become bothersome, the alternative is to switch to one of the second-generation antipsychotic agents with no propensity to elevate this hormone.

Prolixin has a moderate effect on weight gain. It is unclear whether this is due to an underlying metabolic change caused by the antipsychotic or to increased appetite. Weight should be monitored closely during therapy, and if weight gain occurs, an intervention program of diet and exercise should be started.

Orthostatic hypotension and anticholinergic side effects are usually not as troubling with Prolixin as they are with the low-potency antipsychotics.

Adverse Reactions and Precautions

Prolixin may cause drowsiness and sedation and impair physical coordination and mental alertness. Patients should avoid potentially dangerous activities, such as driving a car or operating machinery, until they are sure that these side effects will not affect their ability to perform these tasks.

Tardive dyskinesia (TD) is a potential adverse reaction from antipsychotic medications. It is characterized by late-onset abnormal involuntary movements. TD is a potentially irreversible condition with symptoms that commonly include “pill-rolling” movements of the fingers, darting and writhing movements of the tongue, lip puckering, facial grimacing, and other irregular movements. The risk of TD is associated with the duration of exposure to antipsychotic medication, and this risk increases with age. The conventional antipsychotics are associated with a greater risk of TD than the more recent second-generation antipsychotics.

Neuroleptic malignant syndrome (NMS) is a rare, toxic reaction to antipsychotics. The symptoms are severe muscle stiffness, rigidity, elevated body temperature, increased heart rate and blood pressure, irregular pulse, and profuse sweating. NMS may lead to delirium and coma. It can be fatal if medical intervention is not immediately provided. There are no tests to predict whether an individual is susceptible to developing NMS when exposed to an antipsychotic. Thus NMS must be recognized early because it is a medical emergency that requires immediate discontinuation of the antipsychotic, hospitalization, and intensive medical treatment.

Antipsychotics can lower the seizure threshold and induce **seizures** in susceptible individuals, especially those with a history of seizure disorder. Patients with a seizure disorder who are receiving anticonvulsants often receive antipsychotics without any increase in seizures.

Use in Pregnancy and Breastfeeding: Pregnancy Category C

Prolixin has not been tested in women to determine its safety in pregnancy. The effects of the medication on the developing fetus in pregnant women are unknown. In animal studies, there was no evidence of harm to the fetus when exposed to Prolixin. Animal studies, however, are not always predictive of effects in humans. Women who are pregnant or may become pregnant should discuss this with their physician. Some women may experience a recurrence of their psychosis when they stop Prolixin. In these circumstances, the physician may discuss the need to restart the medication or seek an alternative medication or treatment.

Nursing mothers should not take Prolixin, because small amounts will pass into breast milk and be ingested by the baby. If stopping the antipsychotic is not an alternative, breastfeeding should not be started or should be discontinued.

Possible Drug Interactions

Some medications when taken concomitantly with Prolixin may result in drug interactions that alter their levels, which may produce undesired reactions. The possible drug interactions with Prolixin are summarized in the table below.

Prozac (fluoxetine)	Prozac may inhibit the metabolism of Prolixin and increase Prolixin's blood levels, which may increase the side effects and risk for toxicity from Prolixin.
Paxil (paroxetine)	Paxil may inhibit the metabolism of Prolixin and increase Prolixin's blood levels, which may increase the side effects and risk for toxicity from Prolixin.

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Barbiturates	Barbiturates such as phenobarbital may reduce the blood levels of Prolixin and lower its therapeutic effectiveness.
Tricyclic antidepressants (TCAs)	Prolixin may increase the blood levels of TCAs such as Elavil and Sinequan and increase the side effects and risk for toxicity from these antidepressants.
Antacids with aluminum	Antacids containing aluminum salts (e.g., aluminum hydroxide) may impair the gastrointestinal absorption of Prolixin, reducing its therapeutic effectiveness. Take the antacid 1 hour before or 2 hours after Prolixin.
Orap (pimozide)	The coadministration of Prolixin and Orap, another antipsychotic, may produce an additive effect of prolonging cardiac conduction (QT interval) and increase the risk of arrhythmias. Concomitant administration of these two antipsychotics should be avoided.

Patients taking Prolixin should not consume alcohol because the combination may impair thinking, judgment, and coordination.

Overdose

Depression of the central nervous system (CNS) with deep somnolence, low blood pressure, and EPS are common signs of Prolixin overdose. More serious complications may include agitation, restlessness, convulsions, fever, arrhythmias, and coma. The risk of fatality from the overdose depends on the amount of Prolixin ingested and whether it was combined with other medications, especially other CNS depressants.

Any suspected overdose should be treated as an emergency. The person should be taken to the emergency department for observation and treatment. The prescription bottle of medication (and any other medication suspected in the overdose) should be brought as well, because the information on the prescription label can be helpful to the treating physician in determining the number of pills ingested.

Special Considerations

- Do not discontinue your medication without consulting your physician.
- If you miss a dose, take it as soon as possible. If it is close to your next scheduled dose, skip the missed dose and continue on your regular dosing schedule, but do not take double doses.
- Prolixin may be taken with or without food.
- Prolixin may cause sedation and drowsiness, especially during initiation of therapy, and impair your alertness. Use caution when driving or performing tasks that require alertness.
- Store the medication in its originally labeled, light-resistant container, away from heat and moisture. Heat and moisture may precipitate breakdown of your medication.
- Keep your medication out of reach of children.

If you have any questions about your medication, consult your physician or pharmacist.

