



# Stelazine (trifluoperazine)

Generic name: Trifluoperazine

Available strengths: 1 mg, 2 mg, 5 mg, 10 mg tablets;  
10 mg/mL oral concentrate

Available in generic: Yes

Drug class: First-generation (conventional) antipsychotic

## General Information

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**Stelazine (trifluoperazine)** 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.

Stelazine is a high-potency antipsychotic, relative to low-potency first-generation antipsychotics such as Thorazine (chlorpromazine) and Mellaril (thioridazine). Stelazine is moderately sedating and less likely to lower blood pressure. Like other high-potency antipsychotics such as Haldol (haloperidol) and Prolixin (fluphenazine), Stelazine frequently induces EPS.

Stelazine 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, Stelazine 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, Stelazine is discontinued and the mood stabilizer is continued alone. Stelazine is available in generic forms, although it is better known by its brand name.

## Dosing Information

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For treatment of acute psychosis, the usual starting dosage is 2–5 mg two times a day. The dosage is increased as indicated until symptoms improve. Most patients have symptom relief with 15–20 mg/day, given in divided

doses. The maximum dosage should not exceed 40 mg/day. As symptoms abate, the dosage is reduced to a minimum effective dosage, which is the maintenance dosage.

## Common Side Effects

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Patients taking Stelazine may experience sedation and drowsiness accompanied by fatigue. Sedation may be useful early on in therapy to lessen agitation and help the patient sleep, but as acute symptoms improve, this side effect may become bothersome, interfering with daily activities. Over time, most patients develop tolerance to the side effects of the medication. Daytime sedation may be minimized by taking a larger proportion of the divided dosage at bedtime and a small dose in the morning.

Stelazine may induce side effects known as **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.

Stelazine may induce 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.

When a medication inhibits the action of **cholinergic neurons** in the nervous system, it produces an **anticholinergic reaction**, which may produce bothersome symptoms. Anticholinergic side effects from Stelazine may include blurred vision, dry mouth, constipation, and difficulty with urination. Seniors and individuals with a medical condition may be particularly sensitive to anticholinergic side effects. Stelazine also may block a compensatory response—the narrowing of blood vessels—that counterbalances postural change, resulting in a momentary drop in blood pressure when the person rises too rapidly, which may cause dizziness and lightheadedness. This reaction is known as **orthostatic hypotension**. Patients, especially seniors and those taking antihypertensive medications, need to be cautious and rise slowly to allow their body to adjust to the change in position, avoiding a sudden drop in their blood pressure. Orthostatic hypotension and anticholinergic side effects, which occur more frequently with low-potency, first-generation antipsychotics, are usually not as troublesome with the intermediate- and higher-potency agents.

## Adverse Reactions and Precautions

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Stelazine 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.

Stelazine may enhance ultraviolet light absorption in the skin—a reaction known as **photosensitivity**—and predispose the person to sunburn. Patients should avoid prolonged exposure to sunlight, use sunscreen, and wear protective clothing until tolerance is developed to the medication.

Under very hot conditions, patients may be predisposed to heat-related illness and **heatstroke** because antipsychotics may disrupt the body's ability to regulate temperature. Patients should take precautions to protect themselves from prolonged exposure to hot, humid weather. It is important that patients maintain adequate ventilation and stay indoors.

**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

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Stelazine 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 Stelazine. 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 Stelazine. 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 Stelazine, 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

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Certain medications when taken concurrently with Stelazine may result in drug interactions that alter their levels, producing undesired reactions. Use of medications for lowering blood pressure (antihypertensive medications), for example, when taken with Stelazine, should be monitored closely because the antipsychotic medication may lower blood pressure and produce an additive effect with the medication. Medications that act on

the central nervous system (CNS), including benzodiazepines (e.g., Valium), antihistamines, and narcotic pain medications, may possibly increase the risk and severity of CNS-related side effects of antipsychotics, including somnolence, drowsiness, dizziness, and fatigue.

Patients taking Stelazine should not consume alcohol because the combination may worsen depression and sedation and impair thinking, judgment, and coordination.

## Overdose

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Depression of the central nervous system (CNS) with deep somnolence, low blood pressure, and EPS are common signs of Stelazine 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 Stelazine ingested and whether it was combined with other medications, especially 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

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- 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.
- Stelazine may be taken with or without food.
- Stelazine may cause sedation and drowsiness, especially during initiation of therapy, and impair your alertness. Use caution when driving or performing tasks that require alertness.
- Stelazine may enhance ultraviolet light absorption and increase the risk of sunburn. Use a sunscreen and avoid excessive exposure to sunlight.
- 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.*

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