

Piramal Critical Care is a world leader in inhaled anesthetics, intrathecal therapy, and generic injectables, with a strong presence in more than 100 countries.

Backed by 25 years of quality, dependability, and growth, we are proud to offer a comprehensive U.S. product portfolio and bring you high-quality critical care drugs at affordable prices.

Chlorpromazine Hydrochloride for Injection, USP

For Intravenous Infusion Only

Available in Vials



Available through the wholesaler or distributor of your choice:

WHOLESALER/ DISTRIBUTOR	25 Single-Dose Vials in a carton: NDC 66794-249-42 Chlorpromazine Hydrochloride Injection, USP 25 mg/1mL (25 mg/mL) Catalog Numbers	25 Single-Dose Vials in a carton: NDC 66794-250-42 Chlorpromazine Hydrochloride Injection, USP 50 mg/2 mL (25 mg/mL) Catalog Numbers
Cardinal	5959424	5959432
Cencora	10295608	10295734
McKesson	3004272	3004280
Morris & Dickson	443382	443556

ABBREVIATED PRESCRIBING INFORMATION

DESCRIPTION:

Chlorpromazine HCl USP is chemically designated as 2-chloro-10-[3-(dimethylamino)propyl] phenothiazine monohydrochloride. Each mL contains chlorpromazine hydrochloride USP 25 mg, ascorbic acid 2 mg, sodium metabisulfite 1 mg, sodium sulfite 1 mg and sodium chloride 6 mg in Water for Injection. pH is 3.4 to 5.4.

CLINICAL PHARMACOLOGY:

The principal pharmacological actions are psychotropic. It also exerts sedative and antiemetic activity. Chlorpromazine has actions at all levels of the central nervous system—primarily at subcortical levels—as well as on multiple organ systems. Chlorpromazine has strong antiadrenergic and weaker peripheral anticholinergic activity; ganglionic blocking action is relatively slight. It also possesses slight antihistaminic and antiserotonin activity. The precise mechanism whereby the therapeutic effects of chlorpromazine are produced is not known.

PHARMACEUTICAL FORM: Solution for injection.

THERAPEUTIC INDICATIONS:

For the treatment of schizophrenia; to control nausea and vomiting; for relief of restlessness and apprehension before surgery; for acute intermittent porphyria; as an adjunct in the treatment of tetanus; to control the manifestations of the manic type of manic-depressive illness; for relief of intractable hiccups; for the treatment of severe behavioural problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyperexcitable behaviour (out of proportion to immediate provocations), and in the short-term treatment of hyperactive children who show excessive motor activity with accompanying conduct disorders consisting of some or all of the following symptoms: impulsivity, difficulty sustaining attention, aggressivity, mood lability, and poor frustration tolerance.

DOSAGE AND ADMINISTRATION:

Adults:

- Dosage for adults should be tailored to the individual, with gradual increases until symptoms are controlled and reduced to a maintenance level over time; increase parenteral doses only if no hypotension occurs.
- Specific intramuscular dosages are recommended for various conditions: 25 mg starting dose for acute psychiatric conditions (increasing as needed), 25-50 mg for nausea, and 12.5-25 mg pre-surgery, with adjustments as necessary for intractable hiccups, porphyria, and tetanus.
- For intravenous use, dilute chlorpromazine and administer slowly with close monitoring of blood pressure, starting at low doses and adjusting based on the patient's response.

Elderly Patients:

- Dosages in the lower range are sufficient for most elderly patients. Dosage should be tailored to the individual, response carefully monitored, and dosage adjusted accordingly. Dosage should be increased more gradually in elderly patients.

Pediatric Patients (6 months to 12 years of age):

- Chlorpromazine should generally not be used in pediatric patients under 6 months of age except, potentially lifesaving. Dosage and frequency of administration should be adjusted according to the severity of the symptoms and response of the patient.

[For information on dosage, how to prepare and administer for each indication, see the full prescribing information.]

CONTRAINDICATIONS:

Do not use in patients with known hypersensitivity to phenothiazines. Do not use in comatose states or in the presence of large amounts of central nervous system depressants (alcohol, barbiturates, narcotics, etc.). [Please refer to the full prescribing information.]

WARNINGS AND PRECAUTIONS:

Chlorpromazine carries significant risks in elderly patients with dementia-related psychosis, is not approved for this use, and should be avoided in children at risk for Reye's syndrome. It contains sulfites that may trigger severe allergic reactions, and patients may experience serious side effects such as tardive dyskinesia, neuroleptic malignant syndrome, and falls, requiring risk assessments and monitoring for blood cell abnormalities. Caution is also advised in patients with cardiovascular, liver, or respiratory issues, as chlorpromazine can interact with CNS depressants, affect seizure thresholds, and counteract antihypertensive effects. [For additional information, please refer to the full prescribing information.]

DRUG INTERACTIONS:

Caution is necessary when using chlorpromazine in patients with cardiovascular, liver, renal, or respiratory conditions, as it can exacerbate certain symptoms or lead to complications like aspiration or CNS effects. The drug may interact with CNS depressants, anticonvulsants, anticoagulants, and cancer treatments, requiring dosage adjustments and careful monitoring. Additionally, chlorpromazine may mask symptoms of drug overdose, obscure toxicity signs, and has shown potential genetic effects in rodents, so it should be used carefully in patients with glaucoma and other at-risk groups. [For additional information regarding interactions, please refer to the full prescribing information.]

Usage in Pregnancy Antipsychotic drug exposure in the third trimester poses a risk for neonatal extrapyramidal and withdrawal symptoms. Reported complications include agitation, tremor, respiratory distress, and feeding issues, with varying severity. Chlorpromazine Hydrochloride use during pregnancy is recommended only if benefits outweigh potential fetal risks. Nursing Mothers: Chlorpromazine is found in the breast milk of nursing mothers, and due to the potential for serious adverse reactions in infants, a decision should be made regarding whether to continue nursing or discontinue the drug. Usage in Children: Chlorpromazine should generally not be used in pediatric patients under 6 months of age except where potentially lifesaving. It should not be used in conditions for which specific pediatric dosages have not been established. [For additional information, please refer to the full prescribing information.]

ADVERSE REACTIONS:

Drowsiness, Jaundice, Haematological Disorders, including agranulocytosis, eosinophilia, leukopenia, hemolytic anemia, aplastic anemia, thrombocytopenic purpura and pancytopenia have been reported. agranulocytosis hypotensive effects reversible Q and T wave distortions Neuromuscular reactions include dystonia, motor restlessness, pseudo-parkinsonism and tardive dyskinesia Psychotic symptoms and catatonic-like states Allergic Reactions Occasional dry mouth; nasal congestion; nausea; obstipation; constipation; adynamic ileus; urinary retention; priapism; miosis and mydriasis; atonic colon; ejaculatory disorders/impotence. [For additional information, please refer to the full prescribing information.]

STORAGE:

Protect from light, or discoloration may occur. Slight yellowing will not alter potency. Discard if markedly discoloured. Store at 20° to 25°C (68° to 77°F), excursions permitted to 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature]. Protect from freezing. Discard Unused portion. [For additional information, please refer to the full prescribing information.]

HOW SUPPLIED:

Chlorpromazine Hydrochloride Injection, USP 25 mg/mL is available in the following packages: 1 mL fill in 2 mL single-dose vial packaged in 25s
2 mL fill in 2 mL single-dose vial packaged in 25s



- Full prescribing information of Chlorpromazine Hydrochloride 25mg and 50 mg can be seen at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=251ee159-bcf1-01f6-e063-6394a90aa414>
- Adverse events should be reported to Piramal Critical Care at <http://pcc-chex.force.com/SiteComplaintForm> or email us at pv.safety@piramal.com.
- You are encouraged to report adverse events of prescription drugs to the FDA. Visit MedWatch or call 1-800-FDA-1088.



Piramal Critical Care, Inc.
3950 Schelden Circle
Bethlehem, PA 18017, USA
800-414-1901 • pcc.customerservice@piramal.com
piramalcriticalcare.us

Piramal, Piramal Critical Care, the Piramal logo, and other brands are trademarks of a Piramal company. © 2025 Piramal Critical Care, Inc.

MKT-CHLO-0004 FEB 2025