ChlorproMAZINE HCl
Oral Concentrate, USP

30 mg/mL | 100 mg/mL

* Hydrochloride (HCl)

**MANUFACTURED BY**
Genus Lifesciences, Inc.
514 N 12th Street, Allentown, PA 18102

**DISTRIBUTED AND MARKETED BY**
Arbor Pharmaceuticals, LLC Atlanta, GA 30328
Phone: (866) 516-4950
Websites: www.arborpharma.com
www.chlorpromazinehcl.com

**NDC CODE**
NDC 24338-403-12: 30 mg/mL, 120 mL bottle
NDC 24338-410-24: 100 mg/mL, 240 mL bottle

**MINIMUM ORDER QUANTITY**
One 120 mL bottle or one 240 mL bottle

**HOW SUPPLIED**
30 mg/mL: 120 mL bottle
100 mg/mL: 240 mL bottle

**DATED ITEMS**
The expiration date is printed on each bottle

**PRESCRIPTION LEGEND**
Prescription only

**SPECIAL STORAGE REQUIREMENTS**
Store at 20° to 25°C (68° to 77°F); excursions permitted to 15° to 30°C (59° to 86°F)
Protect from Light
No Refrigeration Needed

**HOW TO ORDER**
Ordering available through wholesalers

**PRODUCT INFORMATION**
For medical information:
Arbor Pharmaceuticals: (866) 516-4950
or medinfo@arborpharma.com

To report an adverse event:
Arbor Pharmaceuticals: (866) 516-4950
or aereports@arborpharma.com

FDA: 1-800-FDA-1088 (1-800-332-1088)
or www.fda.gov/medwatch

**DOSAGE AND STRENGTH**
30 mg/mL oral concentrate
100 mg/mL oral concentrate

**IMPORTANT SAFETY INFORMATION**

**WARNING: INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS**
See full Prescribing Information for complete boxed warning.
- Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death.
- Chlorpromazine hydrochloride is not approved for the treatment of dementia-related psychosis.

Please see additional Important Safety Information throughout, and the accompanying full Prescribing Information, including Boxed Warning.
**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.).

**WARNINGS AND PRECAUTIONS:**

**Increased Mortality in Elderly Patients with Dementia-Related Psychosis:**
Elderly patients with dementia-related psychosis treated with antipsychotic drugs are at an increased risk of death. Chlorpromazine hydrochloride is not approved for the treatment of dementia-related psychosis (see BOXED WARNING).

The extrapyramidal symptoms which can occur secondary to chlorpromazine hydrochloride may be confused with the central nervous system signs of an undiagnosed primary disease responsible for the vomiting, e.g., Reye's syndrome or other encephalopathy. The use of chlorpromazine hydrochloride and other potential hepatotoxins should be avoided in children and adolescents whose signs and symptoms suggest Reye's syndrome.

**Tardive Dyskinesia:**
Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements, may develop in patients treated with antipsychotic drugs. Increased duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase the risk of developing the syndrome and the likelihood that it will become irreversible. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. Antipsychotics should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. The need for continued treatment should be reassessed periodically.

**Neuroleptic Malignant Syndrome (NMS):**
A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. Clinical manifestations of NMS are hyperpyrexia, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, tachycardia, diaphoresis and cardiac dysrhythmias).

Discontinue antipsychotic drugs and other drugs not essential to concurrent therapy immediately following a confirmed NMS diagnosis. If a patient requires antipsychotic drug treatment after recovery from NMS, the potential reintroduction of drug therapy should be carefully considered. The patient should be carefully monitored since NMS recurrence has been reported.

An encephalopathic syndrome (characterized by weakness, lethargy, fever, tremulousness and confusion, extrapyramidal symptoms, leukocytosis, elevated serum enzymes, BUN and FBS) has occurred in a few patients treated with lithium plus an antipsychotic. In some instances, the syndrome was followed by irreversible brain damage.

Patients with bone marrow depression or who have previously demonstrated a hypersensitivity reaction (e.g., blood dyscrasias, jaundice) with a phenothiazine should not receive any phenothiazine, including chlorpromazine hydrochloride, unless in the judgment of the physician the potential benefits of treatment outweigh the possible hazard.

Chlorpromazine hydrochloride may impair mental and/or physical abilities, especially during the first few days of therapy. Therefore, caution patients about activities requiring alertness (e.g., operating vehicles or machinery).

The use of alcohol with this drug should be avoided due to possible additive effects and hypotension.

Chlorpromazine hydrochloride may counteract the antihypertensive effect of guanethidine and related compounds.
Falls:
Chlorpromazine hydrochloride may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other injuries.

Pregnancy and Lactation:
Safety for the use of chlorpromazine hydrochloride during pregnancy has not been established. It is not recommended that the drug be given to pregnant patients except when, in the judgement of the physician, it is essential and only if the potential benefits outweighs the potential risk to the fetus.

Neonates exposed to antipsychotic drugs, during the third trimester of pregnancy are at risk for extrapyramidal and/or withdrawal symptoms following delivery. There have been reports of agitation, hypertonia, hypotonia, tremor, somnolence, respiratory distress and feeding disorder in these neonates. These complications have varied in severity; while in some cases symptoms have been self-limited, in other cases neonates have required intensive care unit support and prolonged hospitalization.

Chlorpromazine hydrochloride should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

There is evidence that chlorpromazine hydrochloride is excreted in the breast milk of nursing mothers and there is potential for serious adverse reactions in nursing infants. A decision should be made whether to discontinue nursing or discontinue the drug.

Leukopenia, Neutropenia and Agranulocytosis:
In clinical trial and post marketing experience, events of leukopenia/neutropenia and agranulocytosis have been reported temporally related to antipsychotic agents. Patients with pre-existing low white blood cell count or a history of drug induced leukopenia/neutropenia should have their complete blood count monitored. Patients with neutropenia should be carefully monitored for fever or other symptoms or signs of infection and treated promptly if such symptoms or signs occur. Discontinue chlorpromazine in patients with severe neutropenia.

General precautions:
Chlorpromazine hydrochloride should be administered cautiously to persons with cardiovascular, liver or renal disease. There is evidence that patients with a history of hepatic encephalopathy due to cirrhosis have increased sensitivity to the CNS effects of chlorpromazine hydrochloride (i.e., impaired cerebration and abnormal slowing of the EEG).

Because of its CNS depressant effect, chlorpromazine hydrochloride should be used with caution in patients with chronic respiratory disorders such as severe asthma, emphysema and acute respiratory infections, particularly in children (1 to 12 years of age). Chlorpromazine hydrochloride prolongs and intensifies the action of CNS depressants such as anesthetics, barbiturates and narcotics. Chlorpromazine hydrochloride diminishes the effect of oral anticoagulants.

Chlorpromazine hydrochloride may lower the convulsive threshold; dosage adjustments of anticonvulsants may be necessary.

Abrupt Withdrawal:
Like other phenothiazines, chlorpromazine hydrochloride is not known to cause psychic dependence and does not produce tolerance or addiction. There may be, however, following abrupt withdrawal of high-dose therapy, some symptoms resembling those of physical dependence such as gastritis, nausea and vomiting, dizziness and tremulousness. These symptoms can usually be avoided or reduced by gradual reduction of the dosage or by continuing concomitant anti-parkinsonism agents for several weeks after chlorpromazine hydrochloride is withdrawn.

DRUG INTERACTIONS
Chlorpromazine hydrochloride may counteract the antihypertensive effect of guanethidine and related compounds. Chlorpromazine hydrochloride prolongs and intensifies the action of CNS depressants such as anesthetics, barbiturates and narcotics. As with all drugs which exert an anticholinergic effect, and/or cause mydriasis, chlorpromazine hydrochloride should be used with caution in patients with glaucoma. Chlorpromazine hydrochloride diminishes the effect of oral anticoagulants. Phenothiazines can produce alpha-adrenergic blockade. Chlorpromazine hydrochloride may lower the convulsive threshold; dosage adjustments of anticonvulsants may be necessary. Concomitant administration with propranolol results in increased plasma levels of both drugs.

ADVERSE REACTIONS
Possible adverse reactions included: CNS reactions (drowsiness, extrapyramidal symptoms, agitation, dystonia, motor restlessness, pseudo-parkinsonism, sedation, dizziness/vertigo, tremor; adverse behavioral effects); jaundice; cardiovascular reactions (tachycardia, hypotension, EKG changes, and syncope); hematological Disorders (agranulocytosis, eosinophilia, leukopenia, hemolytic anemia, aplastic anemia, thrombocytopenic purpura and pancytopenia); lactation and breast engorgement; autonomic reactions; skin pigmentation and ocular changes.

For further information, please see accompanying complete Prescribing Information for Chlorpromazine Hydrochloride Oral Concentrate, USP, 30 mg/mL and 100 mg/mL.

You are encouraged to report side effects of prescription drugs to Arbor Pharmaceuticals, LLC Medical Information at 1-866-516-4950 or to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.
Eliminates the need for compounding or tablet manipulation

Provides flexible dosing in a variety of liquids and semisolid foods†

Can be stored at room temperature and has a 24-month shelf life

† Add the desired dosage of Concentrate to 60 mL (2 fl oz) or more of diluent just prior to administration. Diluents suggested are: tomato or fruit juice, milk, simple syrup, orange syrup, carbonated beverages, coffee, tea, or water. Semisolid foods suggested are: soups, puddings, etc. | Prepared dose remains stable for 2 hours†