

For the use of Registered Medical Practitioner or Laboratory or Pharmacy

Chlorpromazine Injection IP CEZOCALM Injection

COMPOSITION:

Each ml Contains:
Chlorpromazine IP 25mg
Hydrochloride q.s.
Water for Injection

PHARMACEUTICAL FORM
Liquid Injection

PHARMACOLOGICAL PROPERTIES

ATC code: N05AA01

The principal pharmacologic effects of chlorpromazine are similar to those of other propylamino derivatives of phenothiazine. Chlorpromazine has strong anticholinergic and sedative effects and moderate extrapyramidal effects. Chlorpromazine has strong antiemetic and adrenergic blocking activity, and weak ganglionic blocking, antihistaminic and antiserotonergic activity.

Pharmacokinetic properties

Chlorpromazine is rapidly absorbed from parenteral sites of injection. Chlorpromazine is extensively metabolized in the liver and is excreted in the urine and bile in the form of numerous active and inactive metabolites; there is evidence of enterohepatic recycling. Owing to the first-pass effect, plasma concentrations following oral administration are much lower than those following intramuscular administration. Moreover, there is very wide intersubject variation in plasma concentrations of chlorpromazine and its metabolites, and their therapeutic effect. Although the plasma half-life of chlorpromazine itself has been reported to be only a few hours, elimination of the metabolites may be very prolonged.

Chlorpromazine is very extensively bound to plasma proteins. It is widely distributed in the body and crosses the blood-brain barrier to achieve higher concentrations in the brain than in the plasma.

Chlorpromazine and its metabolites also cross the placental barrier and are excreted in milk.

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 behavioral problems in children (1 to 12 years of age) marked by combativeness and/or explosive hyperexcitable behavior (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.

POSODOLOGY AND METHOD OF ADMINISTRATION

Adults

Adjust dosage to individual and the severity of his condition, recognizing that the milligram for milligram potency relationship among all dosage forms has not been precisely established clinically. It is important to increase dosage until symptoms are controlled. Dosage should be increased more gradually in debilitated or emaciated patients. In continued therapy, gradually reduce dosage to the lowest effective maintenance level, after symptoms have been controlled for a reasonable period.

Increase parenteral dosage only if hypotension has not occurred. Before using IM, see Important Notes On Injection.

ELDERLY PATIENTS

In general, dosages in the lower range are sufficient for most elderly patients. Since they appear to be more susceptible to hypotension and neuromuscular reactions, such patients should be observed closely. Dosage should be tailored to the individual, response carefully monitored, and dosage adjusted accordingly. Dosage should be increased more gradually in elderly patients.

PSYCHOTIC DISORDERS

Increase dosage gradually until symptoms are controlled. Maximum improvement may not be seen for weeks or even months. Continue optimum dosage for 2 weeks; then gradually reduce dosage to the lowest effective maintenance level. Daily dosage of 200 mg is not unusual. Some patients require higher dosages (e.g., 800 mg daily is not uncommon in discharged mental patients).

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.).

DRUG INTERACTIONS

Adrenaline must not be used in patients overdosed with Chlorpromazine.

Anticholinergic drugs may reduce the antipsychotic effect of Chlorpromazine and the mild anticholinergic effect of Chlorpromazine may be enhanced by other anticholinergic drugs possibly leading to constipation, heat stroke, etc.

The action of some drugs may be opposed by Chlorpromazine; these include amphetamine, levodopa, clonidine, guanethidine and adrenaline.

Increases or decreases in the plasma concentrations of a number of drugs, e.g. propranolol Phenobarbital have been observed but were not of clinical significance.

Simultaneous administration of dextroamphetamine and chlorpromazine has been observed to induce a transient metabolic encephalopathy characterised by loss of consciousness for 48-72 hours. It is possible this may occur with Chlorpromazine since it shares many of the pharmacological properties of chlorpromazine.

There is an increased risk of agranulocytosis when neuroleptics are used concurrently with drugs with myelosuppressive potential, such as carbamazepine or certain antibiotics and cytotoxics.

ADVERSE EFFECTS

Note: Some adverse effects of chlorpromazine may be more likely to occur, or occur with greater intensity, in patients with special medical problems, e.g., patients with mitral insufficiency or pheochromocytoma have experienced severe hypotension following recommended doses.

Drowsiness, usually mild to moderate, may occur, particularly during the first or second week, after which it generally disappears. If troublesome, dosage may be lowered.

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 Injection, USP is not approved for the treatment of patients with dementia-related psychosis

The extrapyramidal symptoms which can occur secondary to chlorpromazine 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 and other potential hepatotoxins should be avoided in children and adolescents whose signs and symptoms suggest Reye's syndrome.

Chlorpromazine Hydrochloride Injection contains sodium metabisulfite and sodium sulfite, sulfites that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people.

PREGNANCY AND LACTATION

Pregnancy

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.

Usage in Pregnancy:

Safety for the use of chlorpromazine during pregnancy has not been established. Therefore, it is not recommended that the drug be given to pregnant patients except when, in the judgment of the physician, it is essential. The potential benefits should clearly outweigh possible hazards. There are reported instances of prolonged jaundice, extrapyramidal signs, hyperreflexia or hyporeflexia in newborn infants whose mothers received phenothiazines.

Reproductive studies in rodents have demonstrated potential for embryotoxicity, increased neonatal mortality and nursing transfer of the drug. Tests in the offspring of the drug-treated rodents demonstrate decreased performance. The possibility of permanent neurological damage cannot be excluded.

Nursing Mothers

There is evidence that chlorpromazine is excreted in the breast milk of nursing mothers. Because of the potential for serious adverse reactions in nursing infants from chlorpromazine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

OVERDOSE

Symptoms

Primarily symptoms of central nervous system depression to the point of somnolence or coma. Hypotension and extrapyramidal symptoms.

Other possible manifestations include agitation and restlessness, convulsions, fever, autonomic reactions such as dry mouth and ileus, EKG changes and cardiac arrhythmias.

Treatment

It is important to determine other medications taken by the patient since multiple drug therapy is common in overdose situations. Treatment is essentially symptomatic and supportive. Early gastric lavage is helpful. Keep patient under observation and maintain an open airway, since involvement of the extrapyramidal mechanism may produce dysphagia and respiratory difficulty in severe overdose. Do not attempt to induce emesis because a dystonic reaction of the head or neck may develop that could result in aspiration or vomiting. Extrapyramidal symptoms may be treated with anti-parkinsonism drugs, barbiturates or diphenhydramine. See prescribing information for these products. Care should be taken to avoid increasing respiratory depression.

MODE OF ADMINISTRATION

I.M. USE

SHELF LIFE

24 months from the date of manufacturing.

MODE OF SELLING

Prescription Only Medicine (POM)

**Storage: Store protected from light.
at a temprature not exceeding 30°C.**

Marketed by:



Scan for Batch Certificate



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