Prochlorperazine Edisylate Injection, USP

10 mg

NDC 83634-778-02
10 mg per 2 mL

DESCRIPTION	Multi-Dose Vial
CONCENTRATION	5 mg per mL
CLOSURE	13 mm
UNIT OF SALE	10 Vials
BAR CODED	Yes
STORAGE	Room Temp.

- AP RATED
- NOT MADE WITH NATURAL RUBBER LATEX

PLEASE SEE IMPORTANT SAFETY INFORMATION ATTACHED, INCLUDING BOXED WARNING.
VISIT WWW.AVENACY.COM/PRODUCTS/PROCHLORPERAZINE-EDISYLATE-INJECTION-USP FOR FULL PRESCRIBING INFORMATION.

ORDER THROUGH YOUR WHOLESALER:

STRENGTH	Cardinal	Cencora/ABC	McKesson	Morris Dickson
10 mg per 2 mL	5924576	10289790	2960367	386516

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PROCHLORPERAZINE EDISYLATE Injection, USP

INDICATIONS AND USAGE

- To control severe nausea and vomiting.
- For the treatment of schizophrenia.
- Prochlorperazine Edisylate Injection, USP has not been shown effective in the management of behavioral complications in patients with mental retardation.

IMPORTANT SAFETY INFORMATION

WARNING:

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. ANALYSES OF SEVENTEEN PLACEBO-CONTROLLED TRIALS (MODAL DURATION OF 10 WEEKS), LARGELY IN PATIENTS TAKING ATYPICAL ANTIPSYCHOTIC DRUGS, REVEALED A RISK OF DEATH IN DRUG-TREATED PATIENTS OF BETWEEN 1.6 TO 1.7 TIMES THE RISK OF DEATH IN PLACEBO-TREATED PATIENTS. OVER THE COURSE OF A TYPICAL 10-WEEK CONTROLLED TRIAL, THE RATE OF DEATH IN DRUG-TREATED PATIENTS WAS ABOUT 4.5%, COMPARED TO A RATE OF ABOUT 2.6% IN THE PLACEBO GROUP. ALTHOUGH THE CAUSES OF DEATH WERE VARIED, MOST OF THE DEATHS APPEARED TO BE EITHER CARDIOVASCULAR (E.G., HEART FAILURE, SUDDEN DEATH) OR INFECTIOUS (E.G., PNEUMONIA) IN NATURE. OBSERVATIONAL STUDIES SUGGEST THAT, SIMILAR TO ATYPICAL ANTIPSYCHOTIC DRUGS, TREATMENT WITH CONVENTIONAL ANTIPSYCHOTIC DRUGS MAY INCREASE MORTALITY. THE EXTENT TO WHICH THE FINDINGS OF INCREASED MORTALITY IN OBSERVATIONAL STUDIES MAY BE ATTRIBUTED TO THE ANTIPSYCHOTIC DRUG AS OPPOSED TO SOME CHARACTERISTIC(S) OF THE PATIENTS IS NOT CLEAR. PROCHLORPERAZINE EDISYLATE INJECTION, USP IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS.

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.).
- Do not use in pediatric surgery.
- Do not use in pediatric patients under 2 years of age or under 20 lbs.

  Do not use in children for conditions for which dosage has not been established.

WARNINGS

- Prochlorperazine Edisylate Injection is not approved for the treament of patients with dementia-related psychosis.
- The extrapyramidal symptoms which can occur secondary to prochlorperazine 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 prochlorperazine and other potential hepatotoxins should be avoided in children and adolescents whose signs and symptoms suggest Reye's syndrome.
- Antipsychotic drugs should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that, 1) is known to respond to antipsychotic drugs, and, 2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically. If signs and symptoms of tardive dyskinesia appear in a patient on antipsychotics, drug discontinuation should be considered. However, some patients may require treatment despite the presence of the syndrome.
- A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with antipsychotic drugs. The management of NMS should include 1) immediate discontinuation of antipsychotic drugs and other drugs not essential to concurrent therapy, 2) intensive symptomatic treatment and medical monitoring, and, 3) treatment of any concomitant serious medical problems for which specific treatments are available. There is no general agreement about specific pharmacological treatment regimens for uncomplicated NMS. 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 recurrences of NMS have been reported.
- Prochlorperazine may cause somnolence, postural hypotension, motor and sensory instability, which may lead to falls and, consequently, fractures or other injuries. For patients with diseases, conditions, or medications that could exacerbate these effects, complete fall risk assessments when initiating antipsychotic treatment and recurrently for patients on long-term antipsychotic therapy.
- 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. Because of a possible causal relationship between these events and the concomitant administration of lithium and antipsychotics, patients receiving such combined therapy should be monitored closely for early evidence of neurologic toxicity and treatment discontinued promptly if such signs appear. This encephalopathic syndrome may be similar to or the same as neuroleptic malignant syndrome (NMS).
- 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 prochlorperazine, unless in the judgment of the physician the potential benefits of treatment outweigh the possible hazards.
- Prochlorperazine 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).
- Phenothiazines may intensify or prolong the action of central nervous system depressants (e.g., alcohol, anesthetics, narcotics).
- Prochlorperazine Edisylate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- Caution should be exercised when prochlorperazine is administered to a nursing woman.

PRECAUTIONS

- Leukopenia/neutropenia and agranulocytosis have been reported temporally related to antipsychotic agents. Monitor blood counts and discontinue Prochlorperazine Edisylate at the first sign of a decline of white blood cell count in the absence of causative factors, or if absolute neutrophil count is <1,000/mm3.
- Prochloperazine's antiemetic action may mask signs and symptoms of overdosage or toxicities of other drugs.
- Use cautiously in patients with impaired cardiovascular systems to avoid hypotension.
- Aspiration of vomitus has occurred in postsurgical patients.
- Deep sleep, from which patients can be aroused, and coma have been reported, usually with overdosage.
- Use with caution in patients with glaucoma.
- Use with caution in persons who will be exposed to extreme heat.
- Phenothiazines can diminish the effect of oral anticoagulants.
- Phenothiazines can produce alpha-adrenergic blockade.
- Thiazide diuretics may accentuate the orthostatic hypotension that may occur with phenothiazines.
- Antihypertensive effects of guanethidine and related compounds may be counteracted when used concomitantly with phenothiazines.
- Concomitant use with propranolol may result in increased plasma levels of both drugs.
- Adjustment of anticonvulsant dosage may be necessary.
- Phenothiazines may interfere with metabolism of phenytoin causing phenytoin toxicity.
- Phenothiazines may produce false-positive phenylketonuria (PKU) test results.
- Some patients on long-term antipsychotic therapy may develop tardive dyskinesia. Assess regularly to determine whether to lower the dose or discontinue therapy.
- Prochlorperazine Edisylate may cause dystonia and other neuromuscular reactions. Use under close supervision in children with acute illnesses (e.g., chickenpox, CNS infections, measles, gastroenteritis) or dehydration.
- Do not use phenothiazine derivatives with metrizamide.

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ADVERSE REACTIONS

- Common adverse reactions reported with Prochlorperazine Edisylate include drowsiness, dizziness, amenorrhea, blurred vision, skin reactions.
- Other adverse reactions include: neuromuscular (extrapyramidal) reactions, motor restlessness, dystonia, pseudoparkinsonism, tardive dyskinesia, contact dermatitis, and EKG changes.

OVERDOSAGE

- Symptoms: Primarily involvement of the extrapyramidal mechanism producing dystonic reactions. Symptoms of central nervous system depression to the point of somnolence or coma. Agitation and restlessness may also occur. Other possible manifestations include convulsions, EKG changes and cardiac arrhythmias, fever, and autonomic reactions such as hypotension, dry mouth and ileus.
- Treatment: It is important to determine other medications taken by the patient since multiple drug therapy is common in overdosage situations. Treatment is essentially symptomatic and supportive. Keep patient under observation and maintain an open airway, since involvement of the extrapyramidal mechanism may produce dysphagia and respiratory difficulty in severe overdosage. Extrapyramidal symptoms may be treated with antiparkinsonism drugs, barbiturates, or diphenhydramine. Care should be taken to avoid increasing respiratory depression. If administration of a stimulant is desirable, amphetamine, dextroamphetamine, or caffeine and sodium benzoate is recommended. Stimulants that may cause convulsions (e.g., picrotoxin or pentylenetetrazol) should be avoided.
- If hypotension occurs, the standard measures for managing circulatory shock should be initiated. If it is desirable to administer a vasoconstrictor, norepinephrine or phenylephrine are most suitable. Other pressor agents, including epinephrine, are not recommended because phenothiazine derivatives may reverse the usual elevating action of these agents and cause a further lowering of blood pressure.
- Limited experience indicates that phenothiazines are not dialyzable.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch. Or call 1-800-FDA-1088.

Please see full prescribing information for PROCHLORPERAZINE EDISYLATE Injection, USP.