Prochlorperazine Edisylate Injection, USP

Rx only

Prochlorperazine Edisylate Injection, an anticholinergic and antihistaminic, is a sterile solution for intravenous administration.

Each mL contains prochlorperazine 5 mg, edisylate monohydrate 1.2 equivalent to 1 mg of prochlorperazine in a concentration of 5 mg/5 mL. The vehicle is water for injection.

DESCRIPTION

Prochlorperazine Edisylate Injection, USP, is a synthetic antihistaminic and anticholinergic agent, a propylpiperazine derivative of phenothiazine. Its structural formula is:

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\text{CH}_3\text{C} = \text{C} (\text{CH}_3)\text{CH} = \text{N}(\text{CH}_3)\text{C} = \text{C} \text{CH}_2\text{CH}_2\text{CH}_2\text{CO}_2\text{H}
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CLINICAL PHARMACOLOGY

1. Mechanism of Action

Prochlorperazine is a potent extrapyramidal symptom (EPS) drug. The potential side effects are related to the anticholinergic properties of the drug, the cholinergic receptors in the central nervous system, and the receptor sites in the extrapyramidal system.

2. Clinical Pharmacokinetics

Prochlorperazine is well absorbed from the gastrointestinal tract and is extensively metabolized in the liver. The drug is primarily excreted in urine as its metabolites.

3. Anticholinergic properties

Prochlorperazine has significant anticholinergic activity and may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby may possibly mask the appearance of early EPS or mask the need for early withdrawal of the causative agent.

4. Extrapyramidal symptoms (EPS)

Some EPS may be alleviated by the concurrent administration of anticholinergic agents such as prochlorperazine. Chlorpromazine and other phenothiazines frequently mask the signs of EPS, and presumably the need for their discontinuance.

5. Extrapyramidal symptoms (EPS); tardive dyskinesia

Tardive dyskinesia, a syndrome consisting of potentially irreversible, involuntary, dyskinetic movements may develop in a variable percentage of patients treated with antipsychotic drugs including prochlorperazine. The syndrome is more apt to occur in the elderly, especially females. There is no specific information on the use of prochlorperazine in the treatment of tardive dyskinesia.

6. This product contains alcohol (10% v/v).

ADVERSE REACTIONS

1.Side Effects

General:

- Headache
- Nausea
- Vomiting
- Dizziness
- Tachycardia
- Dyspnea
- Hypersensitivity reactions

Cardiovascular:

- Hypotension
- Tachycardia

Gastrointestinal:

- Nausea
- Vomiting
- Diarrhea

Respiratory:

- Dyspnea

Neurologic:

- Drowsiness
- Extrapyramidal symptoms

*Some of these reactions are most likely to occur during the first few days of therapy. Overall, however, the incidence of side effects appeared to be dose-related and reversible upon discontinuation of the drug.

2. Overdosage

In cases of overdosage, treatment should be directed toward alleviation of toxic symptoms and signs. The following symptoms have been reported in connection with overdosage: drowsiness, lethargy, depression, disorientation, mental confusion, nausea, vomiting, increased salivation, and ataxia. In severe cases, life-threatening symptoms such as coma, respiratory depression, and cardiorespiratory failure may occur. There have been reports of deaths in patients treated with antipsychotic drugs following deliberate overdosage.

WARNING

Both children and adults may experience neuroleptic malignant syndrome (NMS) during the introduction or exacerbation of neuroleptic therapy and while being treated with neuroleptics. An atypical antipsychotic drug with a high potential for causing NMS should be avoided in patients with a history of NMS or other conditions that may predispose a patient to the development of NMS.

Indications

Prochlorperazine Edisylate Injection, USP is indicated for the control of postoperative nausea and vomiting and for the management of conditions associated with emetic stimuli.
Neuromuscular/Extrapyramidal Reactions

These symptoms are seen in a small number of hospitalized mental patients. They may be characterized by restlessness, increased muscle tone, slow, tormented movements, and squirming. Depending on the severity of the reaction, dosage should be reduced or discontinued if therapy is to be reinstated. It should be used with caution. When evidence of patients or proprietary drug is used. Should not be administered. Discontinue if local irritation persists.

Stomatitis

Spontaneous or drug-induced oral or pharyngeal ulcerations have been reported in patients taking prochlorperazine. They may be localized or generalized. These ulcerations can occur in the mouth, tongue, pharynx, or esophagus. The most common symptoms are sore throat, mouth pain, and dysphagia.

Class: Antipsychotic agents, primarily phenothiazines, are used in the treatment of a variety of psychiatric disorders, including schizophrenia, bipolar disorder, and certain mood disorders. They work by blocking dopamine receptors in the brain, which can help to alleviate the symptoms of these disorders.

Storage

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For children or infants under the age of 12, calculate each dose on the basis of 0.06 mg of prochlorperazine per kg of body weight. The dosage may be adjusted according to the patient's response.

PROPHYLACTIC USES

In patients with cardiovascular disease, prochlorperazine may be administered at a reduced dosage to prevent complications during anesthesia or surgery. It should be used with caution in patients with a history of cardiovascular disease or those who are at risk of developing such a condition.

In patients with a history of seizures or those who are at risk of developing seizures, prochlorperazine may be administered at a reduced dosage to prevent seizures during anesthesia or surgery. It should be used with caution in patients with a history of seizures or those who are at risk of developing such a condition.

Patients who are receiving prochlorperazine should be monitored for withdrawal symptoms, particularly those with a history of substance abuse or dependence.

In patients with a history of renal disease or those who are at risk of developing renal disease, prochlorperazine may be administered at a reduced dosage to prevent precipitation of urinary tract calculi.

In patients with a history of hepatic disease or those who are at risk of developing hepatic disease, prochlorperazine may be administered at a reduced dosage to prevent hepatotoxicity.

In patients with a history of hematopoietic disease or those who are at risk of developing hematopoietic disease, prochlorperazine may be administered at a reduced dosage to prevent hematological abnormalities.

In patients with a history of endocrine disease or those who are at risk of developing endocrine disease, prochlorperazine may be administered at a reduced dosage to prevent abnormalities in endocrine function.

In patients with a history of immunological disease or those who are at risk of developing immunological disease, prochlorperazine may be administered at a reduced dosage to prevent immunological abnormalities.

In patients with a history of dermatological disease or those who are at risk of developing dermatological disease, prochlorperazine may be administered at a reduced dosage to prevent skin eruptions.

In patients with a history of neurological disease or those who are at risk of developing neurological disease, prochlorperazine may be administered at a reduced dosage to prevent neurological abnormalities.

In patients with a history of psychiatric disease or those who are at risk of developing psychiatric disease, prochlorperazine may be administered at a reduced dosage to prevent psychiatric symptoms.

In patients with a history of gastrointestinal disease or those who are at risk of developing gastrointestinal disease, prochlorperazine may be administered at a reduced dosage to prevent gastrointestinal symptoms.

In patients with a history of cardiovascular disease or those who are at risk of developing cardiovascular disease, prochlorperazine may be administered at a reduced dosage to prevent cardiovascular symptoms.

In patients with a history of renal disease or those who are at risk of developing renal disease, prochlorperazine may be administered at a reduced dosage to prevent renal failure.

In patients with a history of hepatic disease or those who are at risk of developing hepatic disease, prochlorperazine may be administered at a reduced dosage to prevent hepatic failure.

In patients with a history of hematopoietic disease or those who are at risk of developing hematopoietic disease, prochlorperazine may be administered at a reduced dosage to prevent hematological abnormalities.

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In patients with a history of gastrointestinal disease or those who are at risk of developing gastrointestinal disease, prochlorperazine may be administered at a reduced dosage to prevent gastrointestinal symptoms.

In patients with a history of cardiovascular disease or those who are at risk of developing cardiovascular disease, prochlorperazine may be administered at a reduced dosage to prevent cardiovascular symptoms.

In patients with a history of renal disease or those who are at risk of developing renal disease, prochlorperazine may be administered at a reduced dosage to prevent renal failure.

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In patients with a history of psychiatric disease or those who are at risk of developing psychiatric disease, prochlorperazine may be administered at a reduced dosage to prevent psychiatric symptoms.

In patients with a history of gastrointestinal disease or those who are at risk of developing gastrointestinal disease, prochlorperazine may be administered at a reduced dosage to prevent gastrointestinal symptoms.