Prochlorperazine Edisylate Injection, USP

**INDICATIONS AND USAGE**

Prochlorperazine Edisylate Injection, USP is not approved for the treatment of patients with schizophrenia, although it is effective in the management of the extrapyramidal symptoms occasionally associated with the use of these drugs.

**CONTRAINDICATIONS**

Prochlorperazine Edisylate Injection is contraindicated in patients with known hypersensitivity to prochlorperazine or any of its excipients.

**WARNINGS**

Increased Mortality in Elderly Patients with Dementia-Related Psychosis

There have been reports of deaths in elderly patients with dementia associated with the use of antipsychotics, including atypical antipsychotics. These deaths were generally reported in elderly patients with dementia and generally occurred in patients who were at higher risk for reported adverse events, including those with dementia-related psychosis.

**ADVERSE REACTIONS**

**GI Effects**

In single-agent studies, the most frequent adverse reactions associated with the use of prochlorperazine were nausea and vomiting. These occurred in 25% to 40% of patients. In combination with other drugs, nausea and vomiting were observed in up to 50% of patients. In single-agent studies, the incidence of doses of up to 20 mg was approximately 25% and increased to 40% to 50% at a dose of 40 mg. In combination with other drugs, the incidence of doses of up to 20 mg was approximately 20% and increased to 40% to 50% at a dose of 40 mg.

**Cardiovascular Effects**

**Hypotension**

Hypotension may occur, especially in elderly patients or patients with congestive heart failure, shock, or a history of hypotension. Patients should be monitored for signs of hypotension, and blood pressure should be monitored if necessary. In some cases, the use of vasoconstrictors may be required.

**EKG Changes**

EKG changes—particularly nonspecific, usually reversible Q- and T-wave distortions—have been observed with prochlorperazine. These changes are not associated with clinical symptoms or electrocardiographic abnormalities. The incidence of this effect is dose-related.

**Hypersensitivity Reactions**

There have been occasional reports of urticaria, erythema multiforme, Stevens-Johnson syndrome, and toxic epidermal necrolysis. In some instances, these reactions were fatal.

**General**

The incidence of serious adverse reactions associated with the use of prochlorperazine is not known. However, it is important to consider the risk-benefit ratio in selecting a therapeutic regimen for patients with psychosis. The most frequent adverse reactions associated with the use of prochlorperazine are nausea, vomiting, dizziness, headache, drowsiness, and tiredness.

**PRECAUTIONS**

**Antacid**

Antacids may reduce the absorption of prochlorperazine from the GI tract. Prochlorperazine should be given at least 1 hour before or after antacids.

**Drug Interactions**

Prochlorperazine has been shown to increase the central nervous system depressant effects of other drugs, including alcohol, sedative-hypnotics, opioids, and other psychotropic drugs. The concomitant administration of prochlorperazine with other drugs that may cause sudden hypotension, such as ergot derivatives, should be avoided.

**Pregnancy**

Prochlorperazine is not indicated for the treatment of pregnant women, and females of childbearing age should be advised of the potential risk of adverse effects on the fetus.

**NURSING MOTHERS**

Prochlorperazine is not indicated for the treatment of nursing mothers, and females of childbearing age should be advised of the potential risk of adverse effects on the infant.

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