INDICATIONS

Tigan® is indicated for the treatment of postoperative nausea and vomiting and for nausea associated with gastrointestinal disorders.

CONTRAINDICATIONS

This injectable form of Tigan® is contraindicated in pediatric patients and in patients with known hypersensitivity to trimethobenzamide.

WARNINGS

Tigan® may produce drowsiness. Patients should not operate motor vehicles or other dangerous machinery until they know how the medication affects them. These effects have been observed in patients who have received doses of Tigan®.

Usage in Pregnancy: Trimethobenzamide hydrochloride was studied in reproduction experiments in rats and rabbits and no teratogenicity was suggested. The only effects observed were an increased percentage of embryonic resorptions or stillborn pups in rats administered 20 mg and 100 mg/kg and increased resorptions in rabbits receiving 100 mg/kg. In each study these adverse effects were attributed to one or two dams. The relevance to humans is not known. Since there is no adequate experience in pregnant or lactating women who have received this drug, safety in pregnancy or in nursing mothers has not been established.

Usage with Alcohol: Concomitant use of alcohol with Tigan® may result in an adverse drug interaction.

PRECAUTIONS

Patients with Renal Impairment

In subjects with renal impairment (creatinine clearance ≤ 70 mL/min/1.73m²) dose adjustment such as reducing the total dose administered at each dosing or increasing the dosing interval should be used. The clearance of trimethobenzamide is 7 to 9 hours. Between 50 – 90% of a single dose in humans is excreted unchanged in the urine within 48 – 72 hours. The metabolic degradation of trimethobenzamide in humans is not known. Specifically, it is not known if active metabolites are generated in humans.

Special Populations

Age

The adequacy of trimethobenzamide is not known in pediatric patients with renal impairment. However, it may be anticipated that a decrease in the dosage of trimethobenzamide in elderly patients with renal impairment considering the lower average creatinine clearance in this group. (See PRECAUTIONS: General and DOSAGE AND ADMINISTRATION).

Gender

Systemic exposure to trimethobenzamide was similar between men (N=40) and women (N=28).

Race

Pharmacokinetics appeared to be similar for Caucasians (N=63) and African-Americans (N=12).

Renal Impairment

The clearance of trimethobenzamide is not known in patients with renal impairment. However, it may be anticipated that a decrease in the dosage of trimethobenzamide in elderly patients with renal impairment considering that a substantial amount of excretion and elimination of trimethobenzamide occurs via the kidney. (See PRECAUTIONS: General and DOSAGE AND ADMINISTRATION).

ADVERSE REACTIONS

There have been reports of hypersensitivity reactions and Parkinsonism-like symptoms. There have been reports of blood dyscrasias, blurring of vision, coma, convulsions, depression of mood, diarrhea, diaphoresis, dyskinesia, headache, jaundice, muscle cramps and euphoria. If these occur, the administration of the drug should be discontinued. Allergic-type alolin reactions have been observed. Thereafter, the drug should be discontinued at the first sign of sensitization. These symptoms will usually disappear spontaneously, and treatment may be indicated in some cases.

For medical advice about adverse reactions contact your medical professional. To report SUSPECTED ADVERSE REACTIONS, contact Par Pharmaceutical, Inc. at 1-800-828-9393 or FDA at 1-800-FDA-1088 (1-800-332-1088) or www.fda.gov/medwatch.

DOSAGE AND ADMINISTRATION

(See WARNINGS and PRECAUTIONS.)

Dosage should be adjusted according to the indication for therapy, severity of symptoms and the response of the patient.

Geriatric Patients

Dose adjustment such as reducing the total dose administered at each dosing or increasing the dosing interval should be considered in elderly patients with renal impairment (creatinine clearance ≤ 70 mL/min/1.73m²). Final dose adjustment should be based upon integration of clinical efficacy and safety considerations. (See CLINICAL PHARMACOLOGY and PRECAUTIONS.)

WARNINGS

Drug interacting agents (phenothiazines, barbiturates, belladonna alkaloids) should be exercised in administering Tigan® or other antiemetic agents. In such disorders caution should be exercised in administering Tigan®, particularly to patients who have recently received other CNS-acting agents (phenothiazines, barbiturates, belladonna alkaloids). Patients with pre-existing CNS involvement should be directed toward the restoration of body fluids and electrolyte balance, the relief of fever and relief of the causative disease process. Overhydration should be avoided since it may result in cerebral edema.

The antiemetic effects of Tigan® may mask some of the signs of impending or ongoing CNS dysfunction, such as conditions as appendicitis and obscure signs of toxicity due to overdosage of other drugs.

A large volume of Outline is Rate is 2™. In patients with renal failure, Tigan® should be discontinued. Allergic-type skin reactions have been observed; therefore, the drug should be discontinued at the first sign of sensitization. These symptoms will usually disappear spontaneously, and treatment may be indicated in some cases.