DIMENHYDRINATE INJECTION USP

THERAPEUTIC CATEGORY : ANTIEMETIC

PHARMACOLOGY: While the precise mode of action of dimenhydrinate is not known, it has a depressant action on hyperstimulated labyrinthine functions or associated neural pathways.

INDICATIONS: Prevention and relief of motion sickness and the nausea or vomiting incident to these conditions. The treatment of prophylaxis of the nausea and vomiting of radiation sickness, postoperative vomiting, and drug-induced nausea and vomiting; also for the symptomatic treatment of nausea, vomiting and vertigo due to Ménière's disease and other labyrinthine disturbances.

CONTRAINDICATIONS: Neonates and patients with a history of hypersensitivity to dimenhydrinate or its components (diphenhydramine or 8-chlorotheophylline) should not be treated with dimenhydrinate.

WARNINGS: Antiemetics must be used with caution since they may mask the presence of underlying organic abnormalities or the toxic effects of certain antibiotics and other drugs, particularly those drugs causing ototoxicity.

Occupational hazards: Patients receiving dimenhydrinate should be cautioned against operating automobiles or dangerous machinery because of the drowsiness associated with the drug. If drowsiness is excessive, dosage should be reduced.

PRECAUTIONS: Rarely, prolonged therapy with antihistaminic drugs can produce blood dyscrasia. Dimenhydrinate should be used with caution in patients in whom anticholinergics may aggravate other clinical conditions (i.e.; prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, bladder-neck obstruction, narrow-angle glaucoma, bronchial asthma, or cardiac arrhythmias).

An addictive effect may be produced if alcohol or other CNS depressant drugs are given concomitantly with dimenhydrinate.

Pregnancy: The use of dimenhydrinate by women who are pregnant or may become pregnant requires that the potential benefits be weighed against the potential hazards.

Labour and Delivery: The safety of dimenhydrinate injection given during labour and delivery has not been established. Reports have indicated dimenhydrinate may have oxytocic effect. Caution is advised when this effect is unwanted or in situations where it may prove detrimental.

Nursing Mothers: Small amounts of dimenhydrinate are excreted in breast milk. Because of the potential for adverse reactions in nursing infants from dimenhydrinate, 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.

ADVERSE EFFECTS: Drowsiness may be experienced by some patients, especially at high dosages. Dizziness may also occur. Symptoms of dry mouth, lassitude, excitement and nausea have been reported.

OVERDOSE: ***Symptoms:*** Drowsiness is the usual clinical side effect. Convulsions, coma and respiratory depression may occur with massive overdosage.

Children are very susceptible to the convulsant action of antihistamines and doses of 150 to 800 mg of diphenhydramine in children aged 1½ to 3½ have been reported to produce convulsions. A suspected dose of 700 mg of dimenhydrinate produced death in a 22-month-old boy and a dose greater than 800 mg directly caused death in a 2-year-old boy. There has been a report of hallucinations after ingesting 500 mg of diphenhydramine HCl as well as a few reports of delirium and hallucinations following the ingestion of approximately 750 mg of dimenhydrinate. A single case of severe delirium, closely resembling atropine poisoning and with possible extrapyramidal symptoms, following ingestion of a massive overdose of dimenhydrinate taken by an 18-year-old man has been reported.

Treatment: No specific antidote is known. If respiratory depression occurs, mechanically assisted respiration should be initiated and oxygen administered. Convulsions should be treated with appropriate doses of diazepam. Phenobarbital (5 to 6 mg/kg) may be given to control convulsions in children.

DOSAGE: Substances which are physically incompatible with injectable solutions of dimenhydrinate include: phenothiazine derivatives, aminophylline, ammonium chloride, sodium amobarbital, diphenylhydantoin, heparin, hydrocortisone sodium succinate, pentobarbital, phenobarbital, thiopental and certain antibiotics.

Adult: Nausea or vomiting may be expected to be controlled for approximately 4 hours with 25 to 50 mg of dimenhydrinate, and prevented by a similar dose every 4 hours. This dosage regimen may cause some degree of drowsiness in some patients and 100 mg every 4 hours may be given in conditions in which drowsiness is not objectionable or is even desirable. For I.M administration, 1 to 2 mL (50 to 100mg) of the 50 mg/mL solution is injected as needed. The preparation designed for I.M use (50 mg/mL) must not be used I.V unless it has been diluted at least 1:10 with a compatible I.V solution such as 0.9% Sodium Chloride Injection USP. The maximum daily dose should not exceed 300 mg for adults.

Children: I.M : 6 to 8 years: 12.5 to 25 mg, 2 or 3 times daily; 8 to 12 years: 25 mg to 50 mg, 2 or 3 times daily; over 12 years: 50 mg, 2or 3 times daily.

AVAILIBILITY: Dimenhydrinate Injections USP 50 mg/mL. Each mL of sterile solution contains dimenhydrinate USP 50 mg in a mixture of propylene glycol (50%) and water for injection. Ampoules of 1mL also contains sulphuric acid to adjust pH, packaged in boxes of 10, Vials of 5 mL also contain methyl paraben 1 mg/mL and propyl paraben 0.1 mg/mL and may also contain sodium hydroxide or hydrochloric acid to adjust pH, packaged in boxes of 10.

STORAGE: Store at room temperature (15 to 30°C). Protect from freezing.

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