PRESCRIBING INFORMATION

[Pr]HYDROXYZINE HYDROCHLORIDE INJECTION USP

50 mg/mL

Anxiolytic - Sedative

Sandoz Canada Inc.
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50 mg/mL

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ACTION AND CLINICAL PHARMACOLOGY

Hydroxyzine is an antihistamine with anticholinergic, antiemetic and sedative properties. It has been considered to be of some value in the short-term, symptomatic management of pathological anxiety, although its effects are generally considered less consistent and weaker than those of the benzodiazepines.

INDICATIONS AND CLINICAL USE

Hydroxyzine Hydrochloride Injection USP may be of value in the symptomatic alleviation of pathological anxiety in patients with psychoneurotic disorders. Injectable hydroxyzine is useful in those situations in which short-term intramuscular administration of the drug is indicated. The injectable preparation has been found useful particularly in the alleviation of acutely disturbed psychoneurotic patients; in the symptomatic management of patients with acute alcoholic withdrawal; and in the alleviation of excessive anxiety and tension prior to surgical procedures. When used as pre and postoperative medication, Hydroxyzine Hydrochloride Injection USP permits reduction in narcotic dosage and controls emesis.

CONTRAINDICATIONS

Hydroxyzine is contraindicated in women of childbearing potential.

When administered to the pregnant mouse, rat and rabbit, hydroxyzine induced fetal abnormalities.

Hydroxyzine is also contraindicated in patients who have shown previous hypersensitivity to this drug.

WARNINGS AND PRECAUTIONS

Since hydroxyzine may produce sedation and drowsiness, patients should be warned against driving or operating dangerous machinery while taking this drug.

In view of its sedative properties, hydroxyzine may potentiate the effects of other central nervous system depressants such as sedatives, hypnotics, narcotics, psychotropic agents and alcohol. Patients should be cautioned not to drink while taking hydroxyzine and reductions in the dosages

may be required if hydroxyzine is used in conjunction with other central nervous system depressants. Hydroxyzine should also be administered cautiously to epileptic patients.

Hydroxyzine Hydrochloride Injection USP should be injected well within the body of a relatively large muscle such as the upper outer quadrant of the buttocks or the lateral thigh. Inadvertent subcutaneous injection may result in significant tissue damage.

ADVERSE REACTIONS

Hydroxyzine Hydrochloride Injection USP may cause sedation, drowsiness and impairment of mental alertness which tend to disappear in a few days of continued therapy or upon reduction of the dose. Anticholinergic activity, including dryness of the mouth have been reported. Involuntary movements, including tremor and convulsions have also occurred. Rarely, blood dyscrasias have been reported.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701D
    Ottawa, Ontario
    K1A 0K9

  Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

OVERDOSAGE

Close monitoring of patient and symptomatic management.

For management of a suspected drug overdose, contact your regional Poison Control Centre.

DOSAGE AND ADMINISTRATION

Hydroxyzine Hydrochloride Injection USP is intended only for intramuscular administration and should not, under any circumstances, be injected subcutaneously, intra-arterially, or intravenously.

The dosage should be individualized and adjusted in accordance with tolerance and the patient's response to therapy.

Adults:
Psychiatric and emotional emergencies, including acute alcoholism: 50 to 100 mg initially, repeated every 4 to 6 hours as needed.

Pre and postoperative adjunctive therapy: 25 to 100 mg. Nausea and vomiting: 25 to 100 mg.

Children:
Over 6 years of age: 2 mg/kg body weight daily divided into four doses. Not recommended in children under 6 years of age.

Symptomatic use for alleviation of excessive anxiety should usually be limited to periods of one week.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Each mL of Hydroxyzine Hydrochloride Injection USP contains: hydroxyzine hydrochloride 50 mg, benzyl alcohol 0.9%, sodium hydroxide to adjust pH and water for injection.

Hydroxyzine Hydrochloride Injection USP, 50 mg/mL, is available in single use amber ampoules of 1 mL, boxes of 10 and in multidose vials of 10 mL, boxes of 1.

Store between 15 and 30°C.