DiphenhydrAMINE Hydrochloride Injection, USP
50 mg/mL
Antihistaminic

ACTION

Diphenhydramine is a potent antihistaminic agent which possesses antipruritic, anticholinergic (antispasmodic), antiemetic and sedative effects.

INDICATIONS

Parenteral administration of diphenhydramine is indicated for its antiallergic, antiemetic and antispasmodic actions, where in the judgement of the physician, prompt action is necessary and oral therapy would be inadequate.

PRECAUTIONS

Avoid subcutaneous or perivascular injection. Single parenteral dosage greater than 100 mg should be avoided, particularly in hypertension and cardiac disease. Patients should be cautioned not to operate vehicles or hazardous machinery until their response to the drug has been determined. Patients receiving diphenhydramine hydrochloride should be cautioned about additive effects with alcohol and other central nervous system depressants (hypnotics, sedatives and tranquilizers).

Diphenhydramine has an atropine-like effect which should be considered when prescribing this product. Use with caution in patients with history of asthma. Safety for use in pregnancy and lactation has not been established. Its use, therefore in such patients should involve consideration of expected benefits and possible risks.

ADVERSE EFFECTS

Drowsiness, dizziness, dryness of mouth, nausea and nervousness may occur. Other infrequently reported effects are vertigo, palpitation, blurring of vision, headache, restlessness, insomnia and thickening of bronchial secretions. Allergic reactions, diarrhea, vomiting and excitation may also occur.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program, collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug, you may notify Canada Vigilance:

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
  -Mail to: Canada Vigilance Program
  Health Canada
  Postal Locator 0701E
  Ottawa, ON K1A0K9

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 the side effect, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

DOSAGE AND ADMINISTRATION

Adults: 10 to 50 mg intravenously or deeply intramuscularly. High dosage 300 to 400 mg daily may be required in acute generalized or chronic urticaria, allergic eczema, bronchial asthma, and status asthmaticus.

Children: 5 mg/kg/24 hours or 150 mg/m^2/24 hours. Maximum daily dosage is 300 mg. Divide into 4 doses, administered intravenously or deeply intramuscularly.

OVERDOSAGE

In the event of overdosage, contact your doctor, hospital, emergency department or regional Poison Control Centre immediately.

CHEMISTRY

Molecular Formula: $C_{17}H_{21}NO \cdot HCl$

Molecular Weight: 291.82

Chemical Name: (2-diphenylmethoxy)-N, N-dimethyl-ethylamine hydrochloride

Description: Diphenhydramine hydrochloride is a crystalline solid with a melting point of 168-172°C. Very slightly soluble in benzene and diethyl ether, sparingly soluble in acetone, freely soluble in alcohol and chloroform, very soluble in water.

AVAILABILITY

Each mL of Diphenhydramine Hydrochloride Injection USP contains diphenhydramine hydrochloride 50 mg, sodium hydroxide and/or hydrochloric acid to adjust pH and water for injection.

Diphenhydramine Hydrochloride Injection USP is available in preservative free 1 mL single-dose vials, trays of 25. Discard unused portion.

Store vials at room temperature (between 15 and 30°C). Protect from freezing and light.

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