

PRESCRIBING INFORMATION

DiphenhydrAMINE Hydrochloride Injection, USP

50 mg / mL

Sterile Solution

For Intravenous or Deep Intramuscular Use

Antihistaminic

Fresenius Kabi Canada Ltd.
165 Galaxy Blvd, Suite 100
Toronto, ON M9W 0C8

Date of Preparation:
September 7, 2023

Submission Control Number: 269697

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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 Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

DOSAGE AND ADMINISTRATION

Adults: 10 to 50 mg intravenously or deeply intramuscularly. High dosage of 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/m²/24 hours. Maximum daily dosage is 300 mg. Divide into 4 doses, administered intravenously or deeply intramuscularly.

OVERDOSAGE

For management of a suspected drug overdose, contact your regional poison control centre.

CHEMISTRY

Molecular Formula: C₁₇H₂₁NO·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 between 168 °C to 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 use vials, trays of 25. Discard unused portion.

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

If you want more information about DiphenhydrAMINE Hydrochloride Injection, USP:

- Talk to your healthcare professional
- Find the full prescribing information that is prepared for healthcare professionals by visiting the Health Canada website (<https://health-products.canada.ca/dpd-bdpp/index-eng.jsp>); the manufacturer's website (<https://www.fresenius-kabi.ca>), or by calling 1-877-821-7724

This prescribing Information was prepared by:

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