CONTRAINDICATIONS

Use in Neonates or Premature Infants: This drug should not be used in neonates or premature infants.

Use in Nursing Mothers: Because of the risk of anticholinergic effects and sedation in the infant,

Use as a Local Anesthetic: Because of the risk of local necrosis, this drug should not be used as a local anesthetic.

Antihistamines are also contraindicated in the following conditions:

Hyper-sensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

WARNINGS

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcers, pyloroduodenal obstruction, symptomatic prostatic hypertrophy, or bladder-neck obstruction.

Local necrosis has been associated with the use of subcutaneous or intradermal use of intravenous diphenhydramine.

Use in Pediatric Patients: In pediatric patients, especially, antihistamines in overdosage may cause hallucinations, convulsions, or death (see WARNINGS and OVERDOSE).

Use in the Elderly (approximately 60 years or older): Antihistamines are more likely to cause dizziness, sedation, and hypotension in elderly patients.

PRECAUTIONS

General: Diphenhydramine hydrochloride has an antiparkinson-like action and, therefore, should be used with caution in patients with a history of bronchial asthma, increased intracranial pressure, hyperthyroidism, cardiovascular disease or hypertension. Use with caution in patients with lower respiratory disease including asthma.

Information for Patients: Patients taking diphenhydramine hydrochloride should be advised that this drug may cause drowsiness and has an additive effect with alcohol.

Patients should be warned about engaging in activities requiring mental alertness such as driving a car or operating appliances, machinery, etc.

Drug Interactions: Diphenhydramine hydrochloride has additive effects with alcohol and other CNS depressants (hypnotics, sedatives, tranquilizers, etc.). MAO inhibitors prolong and intensify the anticholinergic (drying) effects of antihistamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility:

Long-term studies in animals to determine mutagenic and carcinogenic potential have not been performed.

Pregnancy: Pregnancy Category B: Reproduction studies have been performed in rats and rabbits at doses up to 5 times the human dose and have revealed no evidence of impaired fertility or harm to the fetus due to diphenhydramine hydrochloride. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Pediatric Use: Diphenhydramine should not be used in neonates and premature infants (see CONTRAINDICATIONS).

Diphenhydramine may diminish mental alertness, or in the young pediatric patient, cause excitation. Overdosage may cause hallucinations, convulsions, or death (see WARNINGS and OVERDOSE).

See also DOSAGE AND ADMINISTRATION section.

ADVERSE REACTIONS

The most frequent adverse reactions are under-scored:


2. Cardiovascular System: Hypotension, headache, palpitations, tachycardia, extrasystoles.


5. GI System: Epigastric distress, anorexia, nausea, vomiting, diarrhea, constipation.

6. GU System: Urinary frequency, difficult urination, urinary retention, early menses.

7. Respiratory System: Thickening of bronchial secretions, tightness of chest or throat and wheezing, nasal stuffiness.

OVERDOSE

Antihistamine overdosage reactions may vary from central nervous system depression to stimulation. Stimulation is particularly likely in pediatric patients. Atropine-like signs and symptoms: dry mouth, fixed, dilated pupils; flushing; and gastrointestinal symptoms may also occur.

Stimulants should not be used. Vasopressors may be used to treat hypotension.

DOSAGE AND ADMINISTRATION

THIS PRODUCT IS FOR INTRAVENOUS OR INTRA-MUSCULAR ADMINISTRATION ONLY.

Diphenhydramine hydrochloride in the injectable form is indicated when the oral form is impractical. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND THE RESPONSE OF THE PATIENT.

Pediatric Patients, other than premature infants and neonates: 5 mg/kg/24 hr or 150 mg/m2/24 hr. Maximum daily dosage is 300 mg. Divide into four doses, administer intravenously at a rate generally not exceeding 25 mg/min, or deep intramuscularly.

Adults: 10 mg to 50 mg intravenously at a rate generally not exceeding 25 mg/min, or deep intramuscularly. 100 mg if required; maximum daily dosage is 400 mg.
HOW SUPPLIED

Diphenhydramine Hydrochloride Injection, USP is a clear and colorless solution available as:

- 50 mg/mL in a 1 mL prefilled single-use syringe.
- Available in a carton of twenty-four (24) syringes.

NDC 76045-102-10

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature.]

Protect from freezing and light. Retain in carton until time of use.

Do not place syringe on a sterile field.

Instructions for use:

CAUTION: Certain glass syringes may malfunction, break or clog when connected to some Needleless Luer Access Devices (NLADs) and needles. This syringe has a larger internal syringe tip and an external collar (luer adapter). The external collar must remain attached to the syringe. Data show that the syringe achieves acceptable connections with the BD Eclipse™ Needle and the Terumo SurGuard2™ Safety Needle and with the following non-center post NLADs: Alaris SMARTSITE™, B-Braun ULTRASITE™, BD-Q SYTE™, Maximum MAX PLUS™, and B-Braun SAFSITE™. The data also show acceptable connections are achieved to the center post ICU Medical CLAVE™. However, spontaneous disconnection of this glass syringe from needles and NLADs with leakage of drug product may occur. Assure that the needle or NLAD is securely attached before beginning the injection. Visually inspect the glass syringe-needle or glass syringe-NLAD connection before and during drug administration. Do not remove the clear plastic wrap around the external collar.

5. Do not remove plastic wrap around the external collar. Push plunger rod slightly to break the stopper loose while tip cap is still on.

6. Do not remove plastic wrap around the external collar. Remove tip cap by twisting it off.

7. Discard the tip cap.


9. Adjust dose into sterile material (if applicable).

10. Connect the syringe to appropriate injection connection depending on route of administration. Before injection, ensure that the syringe is securely attached to the needle or NLAD.

11. Depress plunger rod to deliver medication.

12. Remove syringe from IV connector (if applicable) and discard into appropriate receptacle. If delivering medication via intramuscular route, do not recap needle.

NOTES:

- All steps must be done sequentially.
- Do not autoclave syringe.
- Do not use this product on a sterile field.
- Do not introduce any other fluid into the syringe at any time.
- This product is for single dose only.

For more information concerning this drug or to report an adverse event please call BD Rx Inc. at 1-866-943-8534.