**CONTRAINDICATIONS**

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

Use in Nursing Mothers: Because of the higher risk of antihistamines for infants generally, and for neonates and premature in particular, antihistamine therapy is contraindicated in nursing mothers.

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: Hypersensitivity to diphenhydramine hydrochloride and other antihistamines of similar chemical structure.

**WARNINGS**

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

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

**Precautions**

As in adults, antihistamines may diminish mental alertness in pediatric patients. In the young pediatric patient, particularly, they may produce excitation.

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

**Pregnancy:** Pregnancy Category B: Diphenhydramine hydrochloride injection, USP has been shown to be somewhat effective in the treatment of uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.

Motion Sickness: For active treatment of motion sickness.

Antiparkinsonism: For use in parkinsonism in the elderly who are unable to tolerate more potent agents; mild cases of parkinsonism in other age groups, and in other cases of parkinsonism in combination with centrally acting anticholinergic agents.

**Antihistamines:** For amelioration of allergic reactions to blood or plasma, in anaphylaxis as an adjunct to epinephrine and other standard measures after the acute symptoms have been controlled, and for other uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.

Diphenhydramine Hydrochloride Injection, USP

**Rx Only**

**DESCRIPTION**

Diphenhydramine hydrochloride is an antihistamine drug having the chemical name 2-(Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride. It occurs as a white, crystalline powder, is freely soluble in water and alcohol and has a molecular weight of 291.82. The molecular formula is C₂₆H₂₃NO·HCl and the structural formula is as follows:

![Structural formula of Diphenhydramine hydrochloride](image)

Diphenhydramine hydrochloride in the parenteral form is a sterile, pyrogen-free solution. Each mL contains a concentration of 50 mg of diphenhydramine hydrochloride and water for injection, for intramuscular or intravenous use. The solution for parenteral use has been adjusted to a pH between 4 and 6.5 with either sodium hydroxide or hydrochloric acid.

**CLINICAL PHARMACOLOGY**

Diphenhydramine hydrochloride is an antihistamine with anticholinergic (drying) and sedative side effects. Antihistamines appear to compete with histamine for cell receptor sites on effector cells.

Diphenhydramine hydrochloride in the injectable form has a rapid onset of action. Diphenhydramine hydrochloride is widely distributed throughout the body, including the CNS. A portion of the drug is excreted unchanged in the urine, while the rest is metabolized via the liver. Detailed information on the pharmacokinetics of Diphenhydramine Hydrochloride Injection is not available.

**INDICATIONS AND USAGE**

Diphenhydramine hydrochloride in the injectable form is effective in adults and pediatric patients, other than premature infants and neonates, for the following conditions when diphenhydramine hydrochloride in the injectable form is impractical.

Antihistaminic: For amelioration of allergic reactions to blood or plasma, in anaphylaxis as an adjunct to epinephrine and other standard measures after the acute symptoms have been controlled, and for other uncomplicated allergic conditions of the immediate type when oral therapy is impossible or contraindicated.

Motion Sickness: For active treatment of motion sickness.

Antiparkinsonism: For use in parkinsonism in the elderly who are unable to tolerate more potent agents; mild cases of parkinsonism in other age groups, and in other cases of parkinsonism in combination with centrally acting anticholinergic agents.

**PEDIATRIC USE:**

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

**OVERDOSAGE**

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.

**DOSE AND ADMINISTRATION**

THIS PRODUCT IS FOR INTRAVENOUS OR INTRAMUSCULAR ADMINISTRATION ONLY.

Diphenhydramine hydrochloride in the injectable form is impractical.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

**ACUTE HYPERSENSITIVITY:** During desensitization reactions, atropine-like symptoms may occur.

**DOSAGE SHOULD BE INDIVIDUALIZED ACCORDING TO THE NEEDS AND 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.

**REFERENCE ID:** 3243048
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.

1. Inspect the outer packaging (blister pack) for:
   Verify:
   - blister integrity
   - expiry date
   - drug name, drug strength
   - dose volume
   - route of administration
   - sterile field applicability

2. Peel open the paper (top web) of the outer packaging that displays the product information to access the syringe. Do not pop syringe through.

3. Bend the plastic part of the outer packaging (thermoform) so as to present the plunger rod for syringe removal.

4. Perform visual inspection on the syringe
   Verify:
   - absence of external particles
   - absence of internal particles
   - solution is clear and colorless
   - expiration date
   - drug name, drug strength
   - dose volume
   - route of administration
   - sterile field applicability
   - integrity of the 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.

BD Simplist™