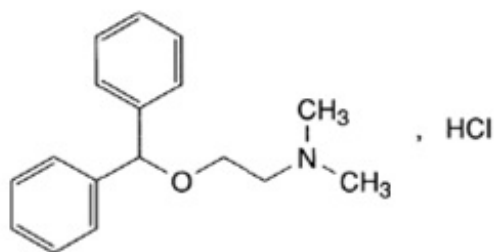


**DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine  
hydrochloride injection  
Micro Labs Limited**

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**Diphenhydramine Hydrochloride Injection, USP**

**DESCRIPTION**

Diphenhydramine hydrochloride, USP is an antihistamine drug having the chemical name 2- (Diphenylmethoxy)-N, N-dimethylethylamine hydrochloride. It occurs as a white, odourless, crystalline powder, is freely soluble in water and alcohol and has a molecular weight of 291.8. The molecular formula is  $C_{17}H_{21}NO \cdot HCl$ . The structural formula is as follows:



Diphenhydramine hydrochloride, USP in the parenteral form is a sterile, pyrogen-free solution available in a concentration of 50 mg of diphenhydramine hydrochloride, USP per mL. The solutions for parenteral use have been adjusted to a pH between 5.0 and 6.0 with either sodium hydroxide or hydrochloric acid and contains 0.1 mg/mL benzethonium chloride as a germicidal agent.

**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 injection, is effective in adults and pediatric patients, other than premature infants and neonates, for the following conditions when diphenhydramine hydrochloride in the oral 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, when oral therapy is impossible or contraindicated, as follows: 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 combinations with centrally acting anticholinergic agents.

## **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 higher risk of antihistamines for infants generally, and for neonates and prematures 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**

Antihistamines should be used with considerable caution in patients with narrow-angle glaucoma, stenosing peptic ulcer, 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 hydrochloride.

### **Use in Pediatric Patients**

In pediatric patients, especially, antihistamines in *overdosage* may cause hallucinations, convulsions, or death.

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.

## **PRECAUTIONS**

### **General**

Diphenhydramine hydrochloride has an atropine-like action and, therefore, should be used with caution in patients with a history of bronchial asthma, increased intraocular 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**

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

Diphenhydramine hydrochloride may diminish mental alertness, or, in the young pediatric patient, cause excitation. Overdosage may cause hallucinations, convulsions, or death (see **WARNINGS** and **OVERDOSAGE**). See also **DOSAGE AND ADMINISTRATION** section

## **ADVERSE REACTIONS**

**The most frequent adverse reactions are underscored.**

1. *General:*Urticaria, drug rash, anaphylactic shock, photosensitivity, excessive perspiration, chills, dryness of mouth, nose, and throat
2. *Cardiovascular System:*Hypotension, headache, palpitations, tachycardia, extrasystoles
3. *Hematologic System:*Hemolytic anemia, thrombocytopenia, agranulocytosis
4. *Nervous System:*Sedation, sleepiness, dizziness, disturbed coordination, fatigue, confusion, restlessness, excitation, nervousness, tremor, irritability, insomnia, euphoria, paresthesia, blurred vision, diplopia, vertigo, tinnitus, acute labyrinthitis, neuritis, convulsions
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

**To report SUSPECTED ADVERSE REACTIONS, contact Micro Labs USA Inc., at 1-855-839-8195 or FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).**

## **OVERDOSAGE**

Antihistamine overdose 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.

*Stimulant*s should not be used.

Vasopressors may be used to treat hypotension.

## **DOSAGE AND ADMINISTRATION**

THIS PRODUCT IS FOR INTRAVENOUS OR INTRAMUSCULAR ADMINISTRATION ONLY.

Diphenhydramine hydrochloride injection, 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/m<sup>2</sup>/24 hr. Maximum daily dosage is 300 mg. Divide into four doses, administered 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 supplied as a clear, colorless sterile solution containing 50 mg diphenhydramine hydrochloride in each milliliter of solution with 0.1 mg/mL benzethonium chloride as a germicidal agent.

10 mL fill in 10 mL vial:

NDC 42571-511-56

**Store at 20° to 25°C (68° to 77°F). [see USP Controlled Room Temperature].**  
**Protect from freezing and light.**

Manufactured by:

**Micro Labs Limited**

Bangalore-560099, INDIA

Manufactured for:

**Micro Labs USA, Inc.**

Somerset, NJ 08873

**Rev. 07/2024**

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 42571-511-56  
diphenhydrAMINE Hydrochloride Injection, USP  
500 mg/10 mL (50 mg/mL)  
For Intravenous or Intramuscular Use  
HIGH POTENCY  
10 mL Multi-Dose Vial  
Rx only



2  
NDC 42571-511-56  
diphenhydrAMINE  
Hydrochloride Injection, USP  
500 mg/10 mL (50 mg/mL)  
For Intravenous or Intramuscular Use  
HIGH POTENCY  
Rx only  
10 mL Multi-Dose Vial  
MICRO LABS

Sterile. Pyrogen-Free.  
**Each mL contains:** Diphenhydramine hydrochloride USP, 50 mg and benzethonium chloride USP 0.1 mg, as a germicidal agent in Water for Injection USP. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.  
**Usual Adult Dosage:** 0.2 mL to 1 mL intravenously or intramuscularly, or more as required. See accompanying prescribing information.  
**Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature].**  
**Protect from freezing and light.**  
**Keep this and all drugs out of the reach of children.** Code: KR/DRUGS/KTK/28/357/2006

Manufactured by:  
**Micro Labs Limited**  
INDIA.

Manufactured for:  
**Micro Labs USA Inc.**  
Somerset, NJ 08873

Rev. 07/2025  
USL-ML14-091





USC-ML14-095

NDC 42571-511-56

**diphenhydrAMINE  
Hydrochloride  
Injection, USP**

**500 mg/10 mL  
(50 mg/mL)**

**For Intravenous or  
Intramuscular Use**

**HIGH POTENCY**

10 mL Multi-Dose Vial

**Rx only**



Sterile. Pyrogen-Free.

**Each mL contains:**

Diphenhydramine hydrochloride USP, 50 mg and benzethonium chloride USP 0.1 mg, as a germicidal agent in Water for Injection USP. The pH may have been adjusted with sodium hydroxide and/or hydrochloric acid.

**Usual Adult Dosage:** 0.2 mL to 1 mL intravenously or intramuscularly, or more as required. See accompanying prescribing information.

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

**Protect from freezing and light.**

NDC 42571-511-56

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**Rev. 07/2025**



N 3 142571 51156 2

NDC 42571-511-56

**diphenhydrAMINE  
Hydrochloride  
Injection, USP**

**500 mg/10 mL (50 mg/mL)**

10 mL Multi-Dose Vial  
**Rx Only**



**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride injection

Product Information				
Product Type		HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42571-511
Route of Administration		INTRAMUSCULAR, INTRAVENOUS		
Active Ingredient/Active Moiety				
Ingredient Name			Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)			DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL
Inactive Ingredients				
Ingredient Name				Strength
BENZETHONIUM CHLORIDE (UNII: PH41D05744)				0.1 mg in 1 mL
HYDROCHLORIC ACID (UNII: QTT17582CB)				
SODIUM HYDROXIDE (UNII: 55X04QC32I)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42571-511-56	1 in 1 CARTON	11/01/2025	
1		10 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA219845	11/01/2025	

**Labeler -**
Micro Labs Limited (862174955)

Establishment			
Name	Address	ID/FEI	Business Operations
Micro Labs Limited		677600482	analysis(42571-511) , label(42571-511) , manufacture(42571-511) , pack(42571-511)