

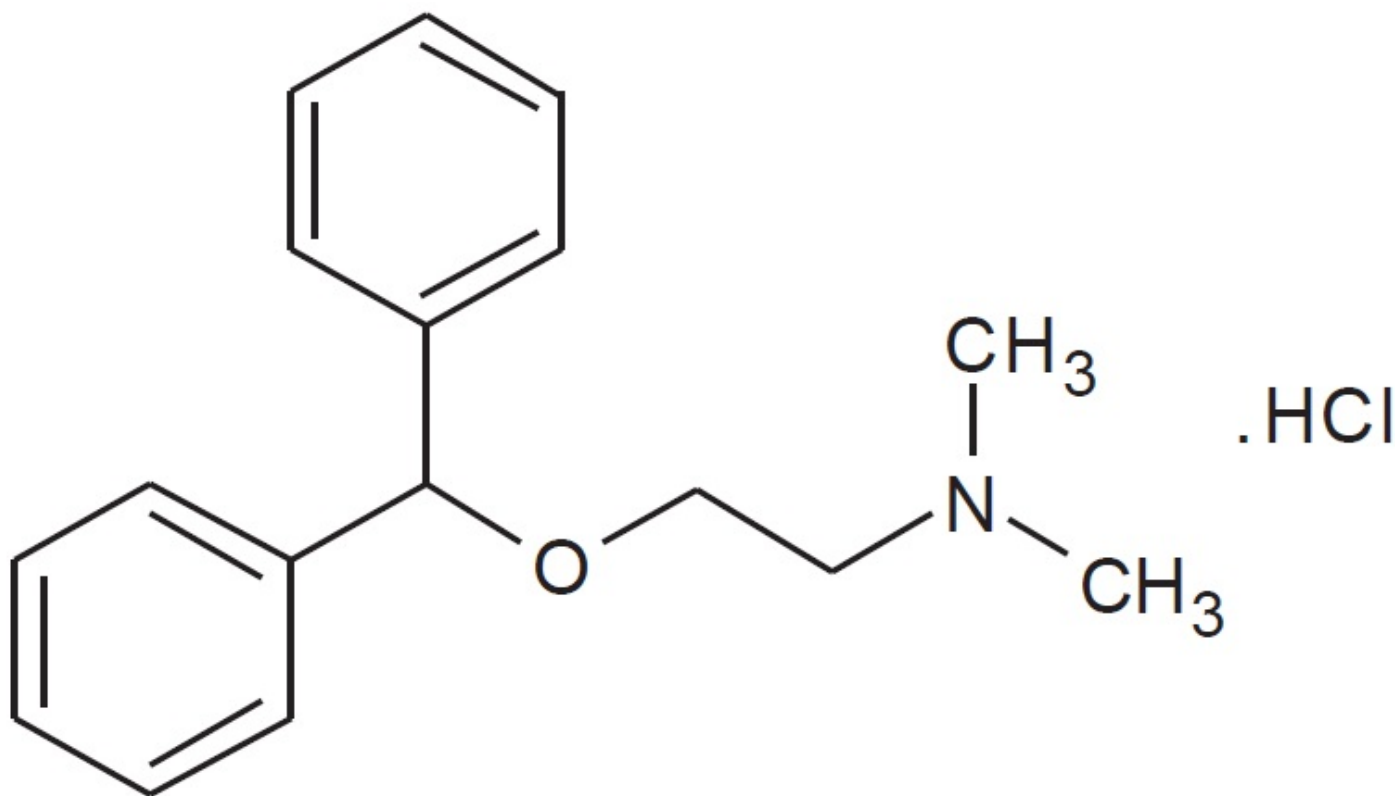
**DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine  
hydrochloride injection**  
**Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.**

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**Diphenhydramine Hydrochloride Injection, USP**  
**Rx only**

**DESCRIPTION**

Diphenhydramine Hydrochloride Injection, USP is a sterile, nonpyrogenic solution for intravenous or deep intramuscular use as an antihistaminic agent. Each mL contains diphenhydramine hydrochloride 50 mg in Water for Injection. pH 4.0 to 6.5; sodium hydroxide and/or hydrochloric acid added, if needed, for pH adjustment. The chemical name of diphenhydramine hydrochloride is 2-(Diphenylmethoxy)-N,N-dimethylethylamine hydrochloride.

The structural formula is as follows:



$C_{17}H_{21}NO \cdot HCl$  MW 291.82

Diphenhydramine hydrochloride occurs as a white crystalline powder and is freely soluble in water and alcohol.

**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 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, USP is not available.

## **INDICATIONS AND USAGE**

Diphenhydramine hydrochloride injection, USP is effective in adults and pediatric patients, other than premature infants and neonates, for the following conditions when 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 combination 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.

### **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**

#### **Teratogenic Effects**

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 **OVERDOSAGE**).

See also **DOSAGE AND ADMINISTRATION** section.

### **ADVERSE REACTIONS**

The most frequent adverse reactions are italicized.

#### **General**

Urticaria; drug rash; anaphylactic shock; photosensitivity; excessive perspiration; chills; dryness of mouth, nose and throat.

#### **Cardiovascular System**

Hypotension, headache, palpitations, tachycardia, extrasystoles.

#### **Hematologic System**

Hemolytic anemia, thrombocytopenia, agranulocytosis.

#### **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.

#### **Gastrointestinal System**

*Epigastric distress*, anorexia, nausea, vomiting, diarrhea, constipation.

#### **Genitourinary System**

Urinary frequency, difficult urination, urinary retention, early menses.

#### **Respiratory System**

*Thickening of bronchial secretions*, tightness of chest and wheezing, nasal stuffiness.

### **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.

## **DOSAGE AND ADMINISTRATION**

THIS PRODUCT IS FOR INTRAVENOUS OR INTRAMUSCULAR ADMINISTRATION ONLY.

Diphenhydramine hydrochloride injection, USP is indicated when the oral form is impractical.

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 hours or 150 mg/m<sup>2</sup>/24 hours. 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.

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

## **HOW SUPPLIED**

Diphenhydramine Hydrochloride Injection, USP 50 mg/mL is a sterile, nonpyrogenic, clear colourless solution, and is supplied as 1 mL single dose vial in package of 25s (NDC 23155-264-41).

### **Storage**

#### **Discard unused portion**

**Protect from light. Keep covered in carton until time of use. Store at 20° to 25°C (68° to 77°F); excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].**

To report SUSPECTED ADVERSE REACTIONS, contact Avet Pharmaceuticals Inc. at 1-866-901-DRUG (3784), or the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Manufactured by:

**Maiva Pharma Private Limited.**

No.32, Sipcot Industrial Complex,  
Phase-1, Hosur-635126, Tamilnadu, INDIA.

Manufactured for:

**Avet Pharmaceuticals Inc.**

East Brunswick, NJ 08816  
1.866.901.DRUG (3784)



Revised: 11/2023

## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**DiphenhydrAMINE Hydrochloride Injection, USP**

**50 mg/mL**

**NDC 23155-264-41**

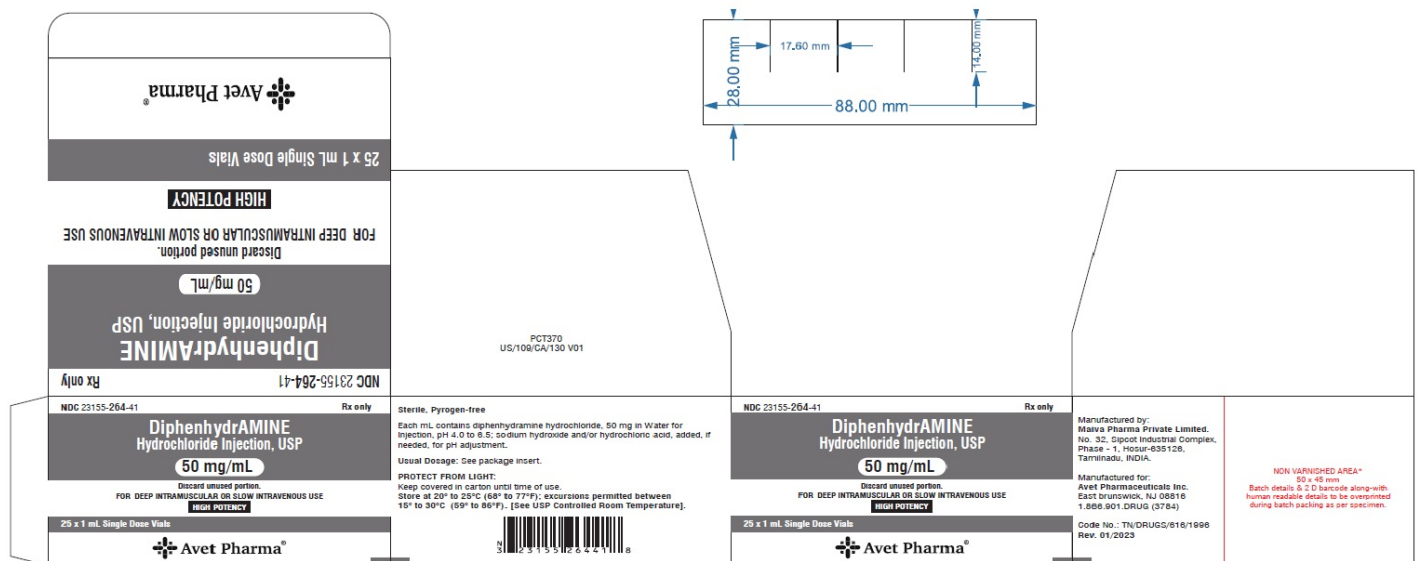
**Rx only**

**Discard unused portion.**

**FOR DEEP INTRAMUSCULAR OR SLOW INTRAVENOUS USE**

**HIGH POTENCY**

**25 x 1mLSingle Dose Vials**



## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**DiphenhydrAMINE Hydrochloride Injection, USP**

**50 mg/mL**

**NDC 23155-264-31**

**Rx only**

**FOR INTRAMUSCULAR OR INTRAVENOUS USE****HIGH POTENCY****1 mL Single Dose Vial**

NDC 23155-264-31


**Rx only**

**PROTECT FROM LIGHT**  
Discard unused portion.  
Mfg. by:  
**Maiva Pharma Private Limited.**  
Mfg. for:  
**Avet Pharmaceuticals Inc.**  
Code No.: TN/DRUGS/616/1996  
Rev. 01/2023  
US/000/LB/000 V01 PLC000

**DiphenhydrAMINE**  
Hydrochloride Injection, USP  
**50 mg/mL**


**FOR INTRAMUSCULAR OR  
INTRAVENOUS USE**  
**HIGH POTENCY**

**1 mL Single Dose Vial**



**NON VARNISHED AREA \***  
13 x 7 mm

Lot: Exp.:



**DIPHENHYDRAMINE HYDROCHLORIDE**

diphenhydramine hydrochloride injection

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:23155-264
<b>Route of Administration</b>	INTRAMUSCULAR, INTRAVENOUS		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII: 8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 mg in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>HYDROCHLORIC ACID</b> (UNII: QTT17582CB)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>WATER</b> (UNII: 059QF0KO0R)	

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:23155-264-41	25 in 1 PACKAGE	06/30/2025	
1	NDC:23155-264-31	1 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	ANDA205336	06/30/2025	

**Labeler -** Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc. (780779901)

**Registrant -** AVET LIFESCIENCES PRIVATE LIMITED (853181664)

## Establishment

Name	Address	ID/FEI	Business Operations
Maiva Pharma Private Limited		725656438	ANALYSIS(23155-264) , MANUFACTURE(23155-264) , label(23155-264) , pack(23155-264)

Revised: 6/2025

Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals Inc.