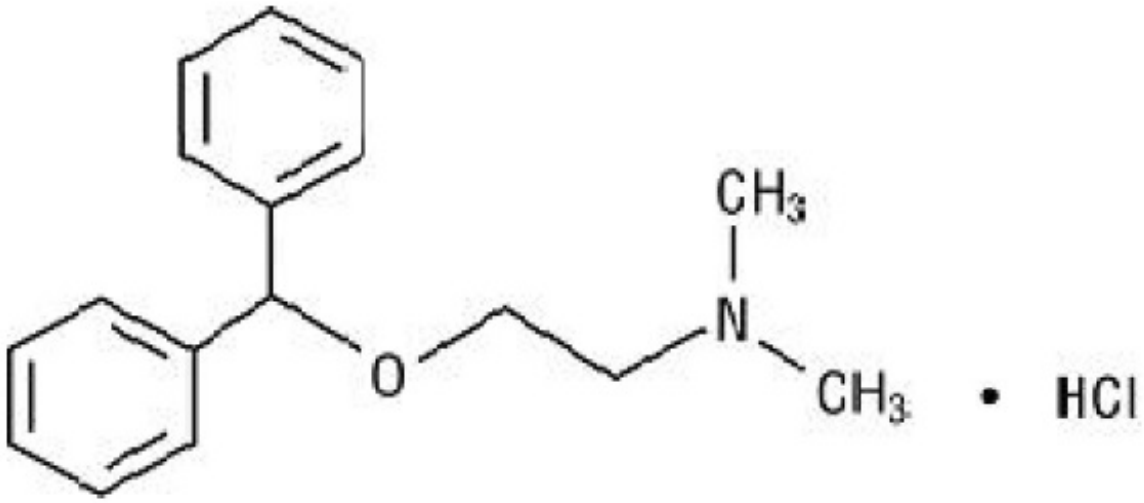
DIPHENHYDRAMINE HYDROCHLORIDE - diphenhydramine hydrochloride injection
Gland Pharma Limited

Diphenhydramine Hydrochloride Injection, USP
Rx only

DESCRIPTION

Diphenhydramine Hydrochloride Injection is a sterile, nonpyrogenic solution for intravenous or deep intramuscular use as an antihistaminic agent. Each mL contains diphenhydramine hydrochloride USP 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 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 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 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^2/24 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 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

1 mL fill in 2 mL single-dose vial packaged in 25s (NDC 68083-611-25)

Storage

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

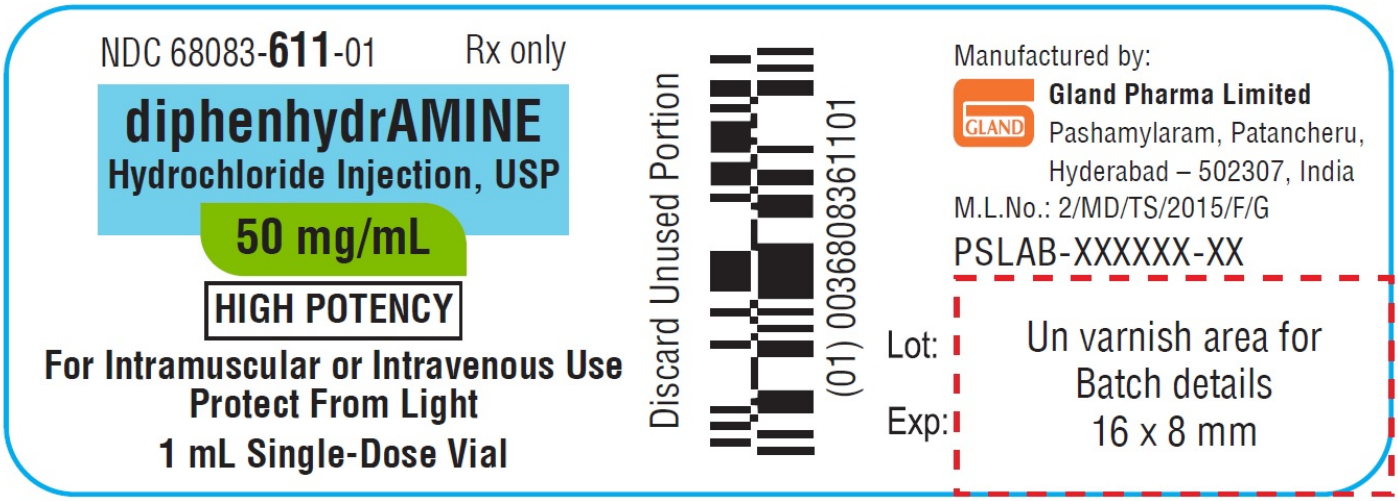
Discard Unused Portion.

To report SUSPECTED ADVERSE REACTIONS, contact Gland Pharma Limited at 609-250-7990, or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. For Product Inquiry call 609-250-7990.

Manufactured by:
Gland Pharma Limited
Pashamylaram, Patancheru,
Hyderabad – 502307, India
Issued: 03/2023

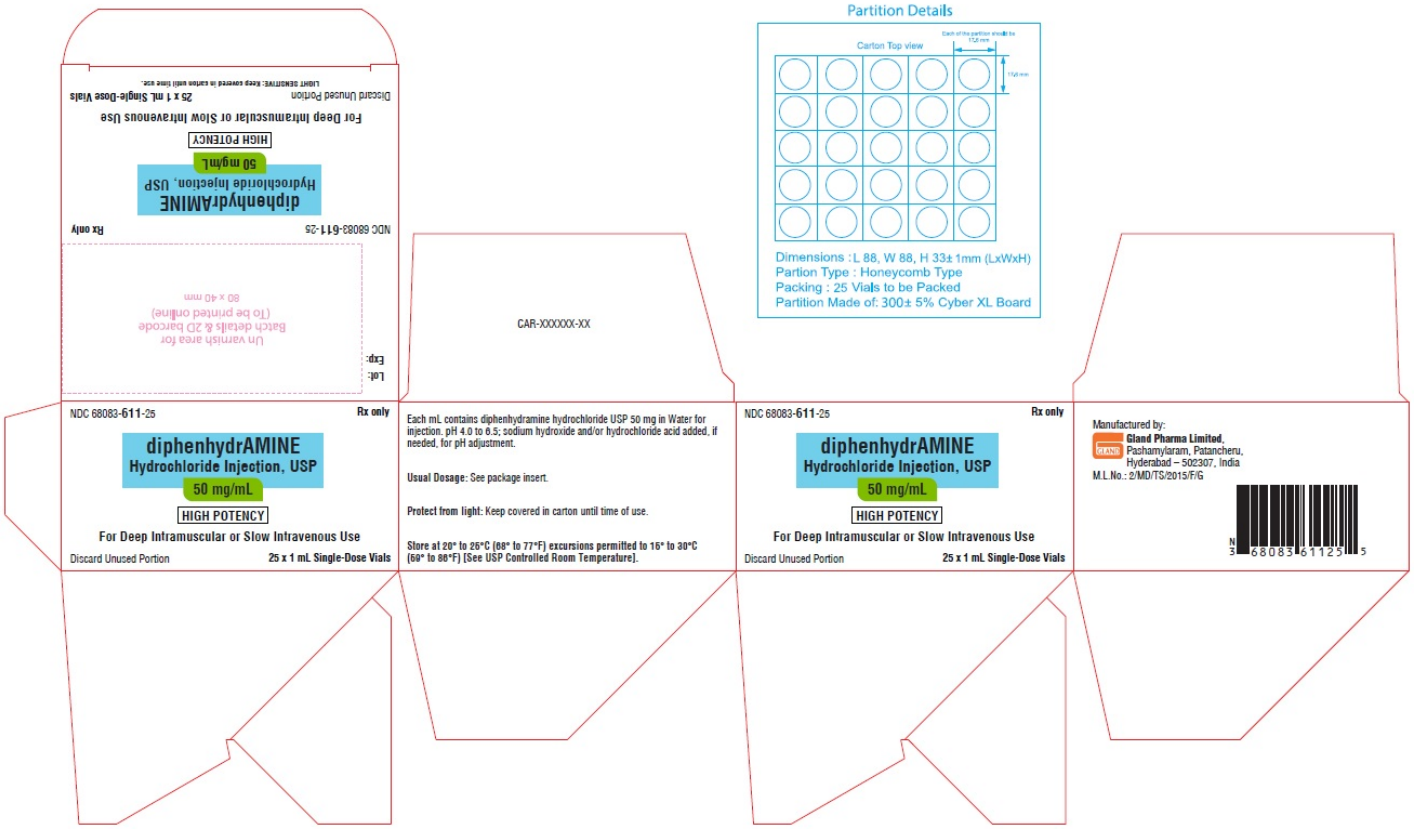
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Container Label
NDC 68083-**611**-01 Rx only
diphenhydrAMINE
Hydrochloride Injection, USP
50 mg/mL
HIGH POTENCY
For Intramuscular or Intravenous Use
Protect From Light
1 mL Single- Dose Vial



Carton Label

NDC 68083-611-25 Rx only
diphenhydrAMINE
Hydrochloride Injection, USP
50 mg/mL
HIGH POTENCY
For Deep Intramuscular or Slow Intravenous Use
Discard Unused Portion
25 x 1 mL Single-Dose Vials



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride injection

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68083-611
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**
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:68083-611-25	25 in 1 CARTON	03/20/2024	
1		1 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA218448	03/20/2024	

Labeler - Gland Pharma Limited (918601238)

Establishment

Name	Address	ID/FEI	Business Operations
Gland Pharma Limited		858971074	ANALYSIS(68083-611) , MANUFACTURE(68083-611) , PACK(68083-611)

Revised: 3/2024 Gland Pharma Limited