DIPHENHYDRAMINE- diphenhydramine hydrochloride injection, solution
Fresenius Kabi USA, LLC

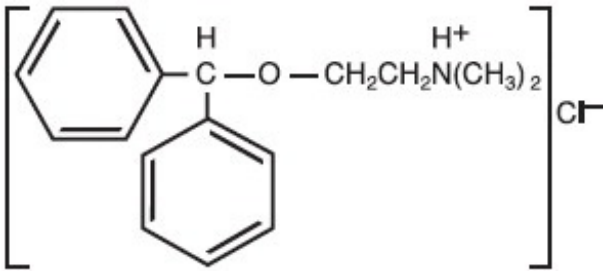
DiphenhydrAMINE Hydrochloride Injection, USP

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.

The structural formula is as follows:



$C_{17}H_{21}NO•HCl$ M.W. 291.82

Diphenhydramine hydrochloride in the parenteral form is a sterile, pyrogen-free solution available in a concentration of 50 mg of diphenhydramine hydrochloride per mL. pH 4.0 to 6.5; sodium hydroxide and/or hydrochloric acid added, if needed, for pH adjustment.

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 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 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

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 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.

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 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/m ^{2}/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 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 in parenteral form is supplied as:

Product Code	**Unit of Sale**	**Strength**	**Each**
660401	NDC 63323-664-01 Unit of 25	50 mg per mL 1 mL fill in a 2 mL vial.	NDC 63323-664-00 1 mL Single Dose Vial

It is supplied as a sterile, pyrogen-free solution containing 50 mg diphenhydramine hydrochloride in each milliliter of solution.

The container closure is not made with natural rubber latex.

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

Protect from light. Keep from freezing.

FRESENIUS KABI
Lake Zurich, IL 60047

www.fresenius-kabi.com/us

45954D

Revised: May 2018

PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine Hydrochloride 1 mL Single Dose Vial Label

660401

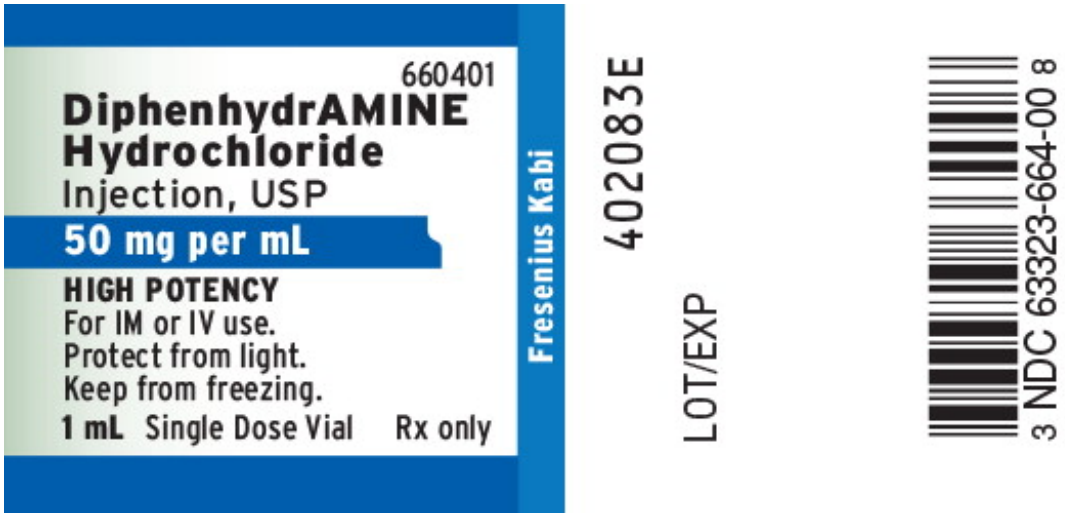
DiphenhydrAMINE Hydrochloride Injection, USP

50 mg per mL

HIGH POTENCY
For IM or IV use.

Protect from light.
Keep from freezing.

1 mL Single Dose Vial Rx only

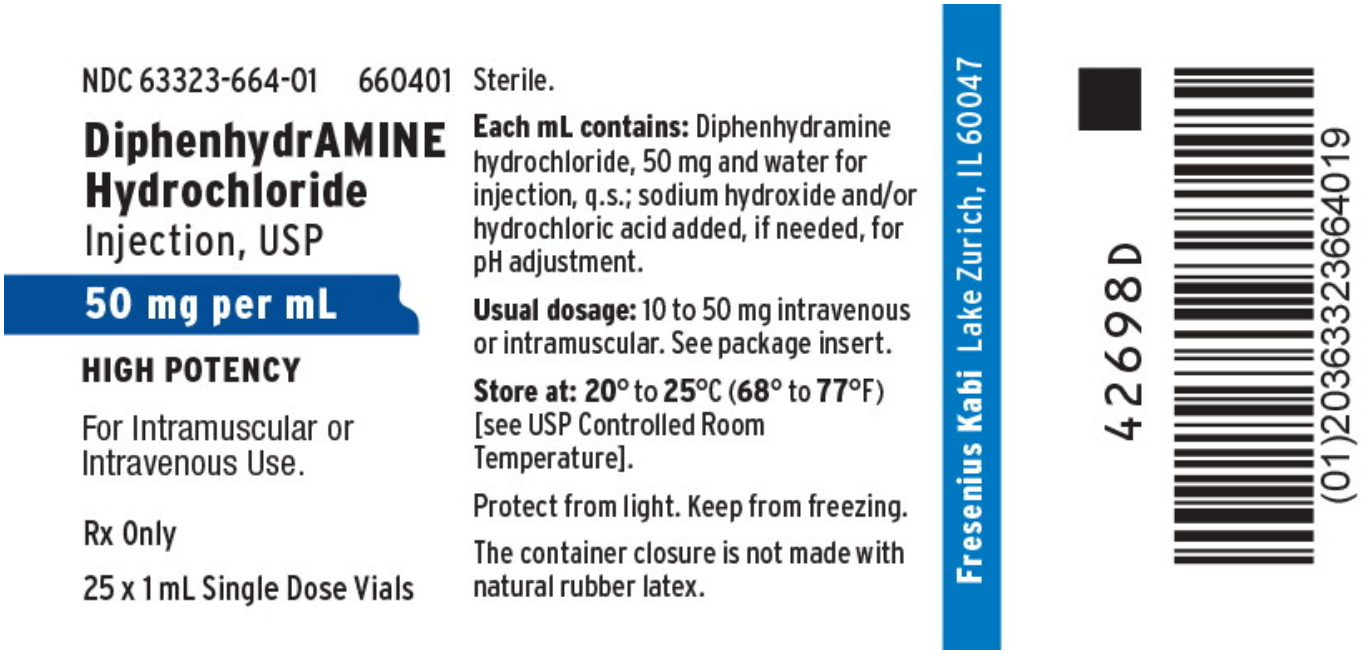


PACKAGE LABEL - PRINCIPAL DISPLAY - Diphenhydramine Hydrochloride 1 mL Single Dose Vial Tray Label
NDC 63323-664-01 660401
DiphenhydrAMINE Hydrochloride Injection, USP

50 mg per mL

HIGH POTENCY
For Intramuscular or Intravenous use.
Rx only

25 x 1 mL
Single Dose Vials



DIPHENHYDRAMINE

diphenhydramine hydrochloride injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63323-664
Route of Administration	INTRAVENOUS, INTRAMUSCULAR		

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)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63323-664-01	25 in 1 TRAY	08/01/2002	
1	NDC:63323-664-00	1 mL in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040466	08/01/2002	

Labeler - Fresenius Kabi USA, LLC (608775388)

Establishment

Name	Address	ID/FEI	Business Operations
Fresenius Kabi USA, LLC		840771732	manufacture(63323-664)

Revised: 10/2019 Fresenius Kabi USA, LLC