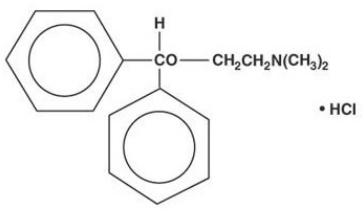
DIPHENHYDRAMINE HCI- diphenhydramine hci injection, solution
HF Acquisition Co LLC, DBA HealthFirst

DIPHENHYDRAMINE HCI INJECTION, USP 50mg/mL 1mL CARP

SPL UNCLASSIFIED

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 C17H21NO • HCl and the structural formula is as follows:



Diphenhydramine hydrochloride in the parenteral form is a sterile, pyrogen-free solution available in a concentration of 50 mg of diphenhydramine hydrochloride per mL 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 & 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.

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 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 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 & 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/m2/24 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 HCI INJECTION, USP is supplied in the following dosage forms.
NDC 51662-1218-1
DIPHENHYDRAMINE HCI INJECTION, USP 50mg/mL 1mL CARP

HF Acquisition Co LLC, DBA HealthFirst
Mukilteo, WA 98275

Also supplied in the following manufactures dosage forms

Diphenhydramine Hydrochloride Injection, USP is available as:

Unit of Sale	Concentration
NDC 0409-2290-31 Carton of 10 Carpujects	50 mg/mL

Carpuject™ Single-use cartridges with Luer Lock are packaged in a Slim-Pak™ tamper detection package. Note that a needle is not included.

Instructions for Use of the Syringe Systems

Instructions for using the Carpuject™ Syringe are available with the reusable Carpuject™ Holder, List 2049-02.

Carpuject™ Single-use cartridges are to be used ONLY with Carpuject™ Holders, List 2049-02.

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.

Distributed by Hospira, Inc., Lake Forest, IL 60045 USA

LAB-1300-1.0

Revised: 04/2018

PRINCIPAL DISPLAY PANEL - 1 mL Carpuject Cartridge Label

1 mL Single-use Carpuject™
Sterile Cartridge Unit with Luer Lock

DiphenhydrAMINE
HCl Injection, USP

50 mg/mL

For Intravenous or Intramuscular Use

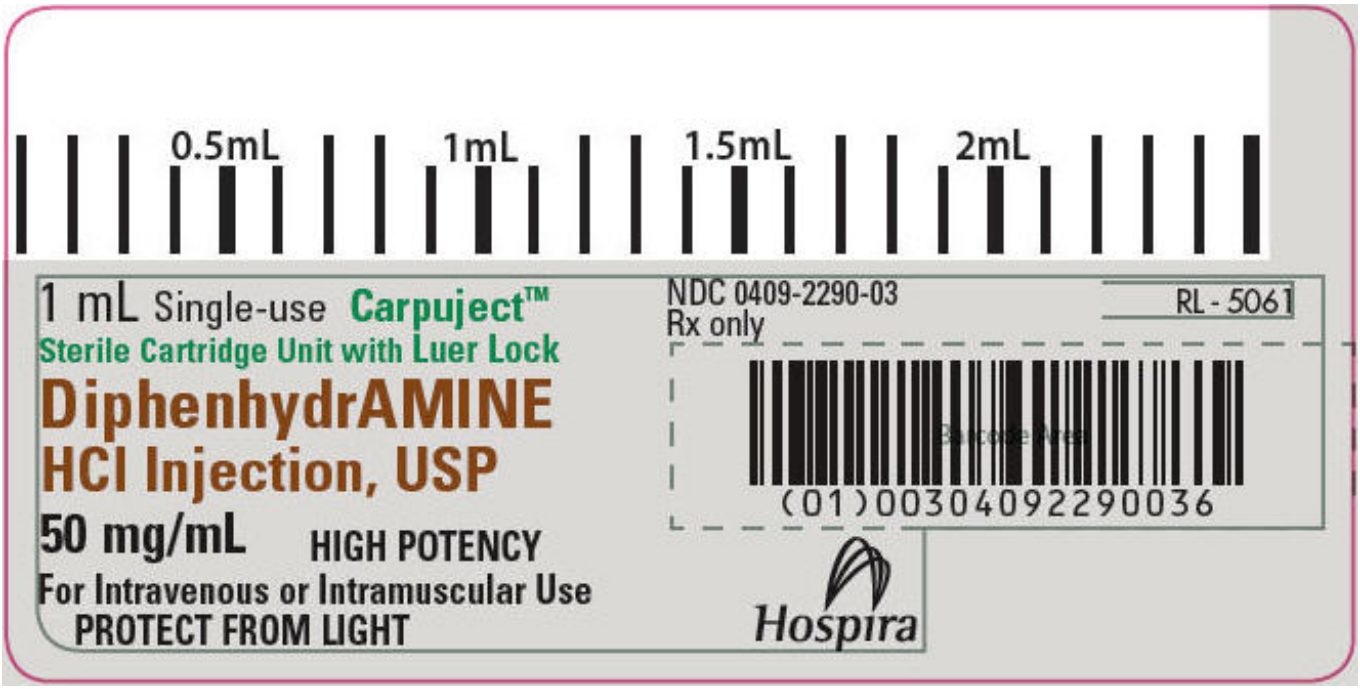
Rx only

HIGH POTENCY
PROTECT FROM LIGHT

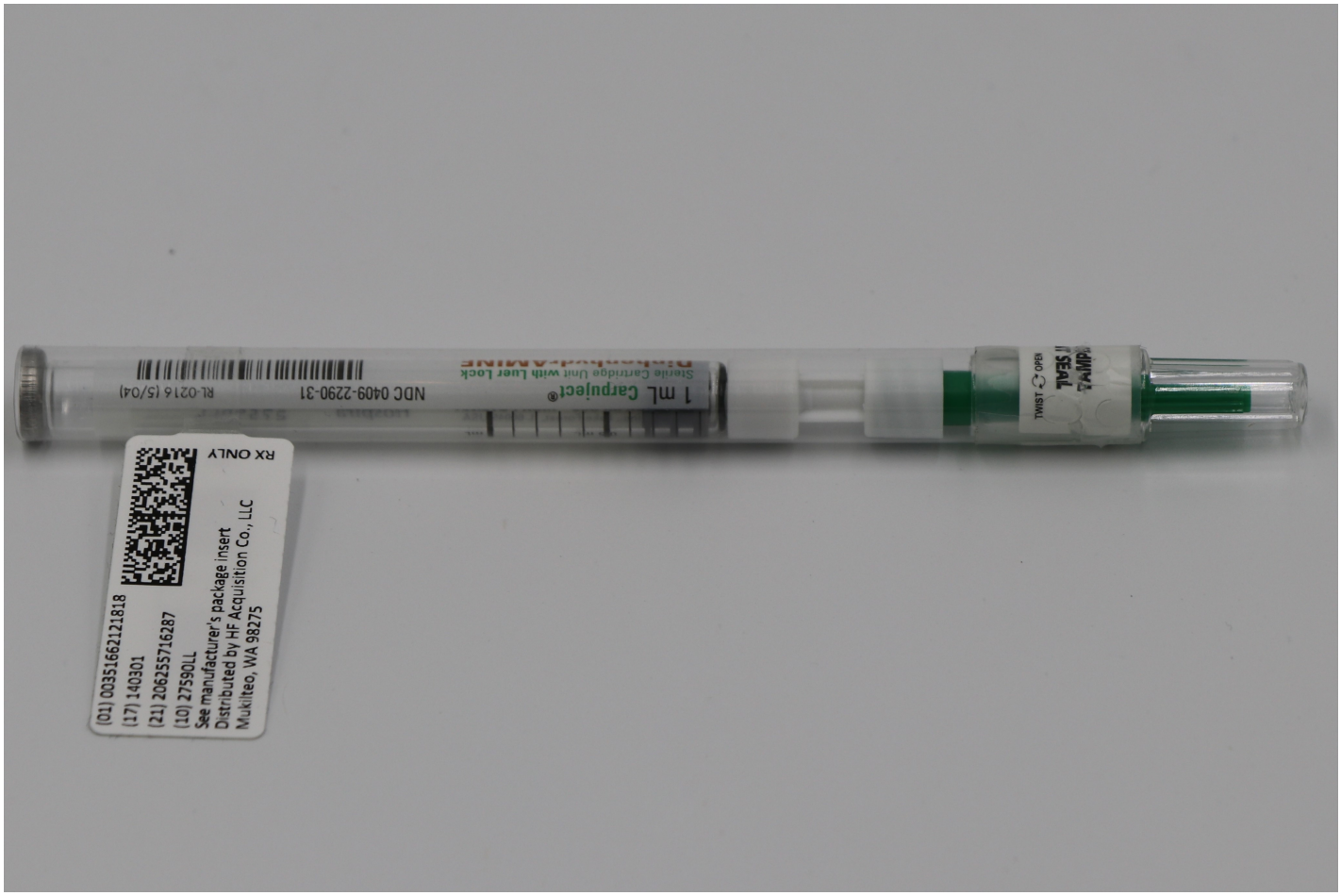
Hospira

NDC 0409-2290-03

RL–5589



PRINCIPAL DISPLAY PANEL - SERIALIZED 1 mL Carpuject Cartridge Label



DIPHENHYDRAMINE HCI

diphenhydramine hcl injection, solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51662-1218(NDC:0409-2290)
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:51662-1218-1	1 mL in 1 CARTRIDGE; Type 7: Separate Products Requiring Cross Labeling	11/19/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040140	11/19/2018	

Labeler - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Registrant - HF Acquisition Co LLC, DBA HealthFirst (045657305)

Establishment

Name	Address	ID/FEI	Business Operations
HF Acquisition Co LLC, DBA HealthFirst		045657305	relabel(51662-1218)

Revised: 2/2020 HF Acquisition Co LLC, DBA HealthFirst