

DIPHENHYDRAMINE HCL- diphenhydramine hcl capsule

A-S Medication Solutions

Drug Facts

Active ingredient (in each capsule)

Diphenhydramine HCL 25 mg

Purpose

Antihistamine

Uses:

Temporarily relieves these symptoms associated with the common cold, hay fever, or other respiratory allergies.

- sneezing
- nasal congestion
- runny nose
- itchy, watery eyes

Warnings:

Do not use

- With any other product containing Diphenhydramine HCL, including one applied topically.

Ask a doctor or pharmacist before use

If you have

- trouble urinating due to enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- if you are taking sedatives or tranquilizers

When using this product

- Avoid alcoholic drinks.
- marked drowsiness may occur.
- excitability may occur, especially in children.
- alcohol, sedatives and tranquilizers may increase drowsiness.
- be careful when driving a motor vehicle or operating machinery.

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children

In case of overdose, get medical help or contact a Poison Control Center right away.

Directions:

- Take every 4-6 hours
- Do not take more than 6 doses in 24 hours.

Adults and children 12 years or over	1 to 2 capsule
Children 6 to under 12 years	1 capsule
Children under 6 years	ask a doctor

Other information:

- Store at room temperature 15-30 degrees C (59-86 degrees F)
- Protect from excessive moisture

Inactive ingredients: Black Iron Oxide, D & C Red #28, FD & C Blue #1, FD & C Red #40, Gelatin, Lactose Monohydrate, Magnesium Stearate, Silicon Dioxide, Sodium Lauryl Sulfate

HOW SUPPLIED

Product: 50090-5716

NDC: 50090-5716-0 30 CAPSULE in a BOTTLE

NDC: 50090-5716-3 20 CAPSULE in a BOTTLE

DIPHENHYDRAMINE HCL



DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-5716(NDC:66424-020)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
D&C RED NO. 28 (UNII: 7671P0Y5NH)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	pink	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	PH014
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5716-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/24/2021	
2	NDC:50090-5716-3	20 in 1 BOTTLE; Type 0: Not a Combination Product	07/02/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/27/2010	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5716) , REPACK(50090-5716)

Revised: 12/2023

A-S Medication Solutions