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

- aAvoid 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

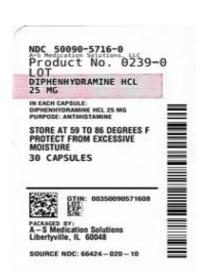
HOW SUPPLIED

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

Active mgreater molecy			
Ingredient Name	Basis of Strength	Strength	
- · · · · · · · · · · · · · · · · · · ·	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg	

Inactive Ingredients			
Ingredient Name	Strength		
FERROSOFERRIC OXIDE (UNII: XM0M87F357)			
D&C RED NO. 28 (UNII: 767IP0Y5NH)			
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			

P	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