

DIPHENHYDRAMINE HCL - diphenhydramine hcl capsule

A-S Medication Solutions

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts

Active ingredient(in each capsule)

Diphenhydramine HCL 50 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 capsule Children under 12 years ask a doctor**25 mg strength is not available in this package. Do not attempt to break capsules.

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

Questions? Adverse drug event call:

1-800-687-0176

HOW SUPPLIED

Product: 50090-4539

NDC: 50090-4539-0 30 CAPSULE in a BOTTLE

NDC: 50090-4539-2 15 CAPSULE in a BOTTLE

NDC: 50090-4539-3 20 CAPSULE in a BOTTLE

NDC: 50090-4539-5 10 CAPSULE in a BOTTLE

NDC: 50090-4539-1 100 CAPSULE in a BOTTLE

Diphenhydramine HCL

NDC 50090-4539-0
A-S Medication Solutions, LLC
Product No. 0241-0
LOT
DIPHENHYDRAMINE
HCL
50 MG

EACH CAPSULE CONTAINS:
DIPHENHYDRAMINE HCL 50 MG

STORE AT 59 TO 86 DEGREES F
PROTECT FROM EXCESSIVE
MOISTURE
30 CAPSULES



GTIN: 00350090453904
LOT:
EXP:
S/N:

PACKAGED BY:
A-S Medication Solutions
Libertyville, IL 60048
MFG: SDA LABORATORIES
GREENWICH, CT 06830
SOURCE NDC: 66424-021-01



DIPHENHYDRAMINE HCL

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-4539(NDC:66424-021)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	50 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	PH013
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-4539-3	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2019	
2	NDC:50090-4539-1	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2019	
3	NDC:50090-4539-5	10 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2019	
4	NDC:50090-4539-0	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2019	
5	NDC:50090-4539-2	15 in 1 BOTTLE; Type 0: Not a Combination Product	09/20/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/27/2010	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-4539) , REPACK(50090-4539)

Revised: 2/2023

A-S Medication Solutions