

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**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: 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 | PH013 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:50090-4539-0 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2019 | |
| 2 | NDC:50090-4539-2 | 15 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2019 | |
| 3 | NDC:50090-4539-3 | 20 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2019 | |
| 4 | NDC:50090-4539-5 | 10 in 1 BOTTLE; Type 0: Not a Combination Product | 09/20/2019 | |
| 5 | NDC:50090-4539-1 | 100 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: 5/2020

A-S Medication Solutions