DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride 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.

0835&0836(box unit)-Major

Active Ingredient (in each banded capsule)

Diphenhydramine HCl... 25 mg

Diphenhydramine HCl... 50 mg

Purpose

Antihistamine

Use

25 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itchy throat and nose
- Temporarily relieves these symptoms due to the common cold:
  - runny nose
  - sneezing

50 MG

- Temporarily relieves these symptoms due to hay fever or other upper respiratory allergies and common cold
  - sneezing
  - runny nose
  - itchy, watery eyes
  - itchy throat and nose

WARNINGS

Do not use

25 MG

- to make a child sleepy
- with any other product containing diphenhydramine, even one used on skin

50 MG
- to make a child sleepy
- with any other product containing diphenhydramine, including one applied topically

Ask a doctor before use if you have

25 MG
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

50 MG
- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist

before use if you are taking sedatives or tranquilizers

When using this product
- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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

25 MG

adults and children 12 years of age and over	1 to 2 capsules
children 6 years to under 12 years of age	1 capsule

children under 6 years of age	do not use this product in children under 6 years of age

50 MG

adults and children 12 years of age and over	1 capsule
children 6 years to under 12 years of age	Ask a doctor, the proper dosage strength is not available in this package**

**Do not attempt to break capsules. The proper dosage strength and dosing information for children under 12 years of age is available on the 25 mg package.

Other Information

- Store at 20°C – 25°C (68°F – 77°F); excursions permitted to 15° – 30°C (59° – 86°F) [See USP Controlled Room Temperature]
- Protect from moisture
- Contains lactose

Inactive Ingredients

D&C Red #28, FD&C Blue #1, FD&C Red #40, Gelatin, Lactose and Starch.

Questions?

Questions or comments? (800) 616-2471

Distributed by

MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233,

Livonia, MI 48152

HOW SUPPLIED

Product: 50090-3788

NDC: 50090-3788-0 8 CAPSULE in a BOTTLE

NDC: 50090-3788-1 10 CAPSULE in a BOTTLE

DIPHENHYDRAMINE HYDROCHLORIDE CAPSULE BANOPHEN (DIPHENHYDRAMINE HCL) CAPSULE

DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-3788(NDC:0904-5306)
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
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)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	pink (half pink and half clear with white powder inside)	**Score**	no score
Shape	CAPSULE	**Size**	14mm
Flavor		**Imprint Code**	CPC;835
Contains			

Packaging

			Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-3788-0	8 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2018	
2	NDC:50090-3788-1	10 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	01/02/2009	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-3788) , REPACK(50090-3788)

Revised: 3/2021 A-S Medication Solutions