DIPHENHYDRAMINE HYDROCHLORIDE- diphenhydramine hydrochloride capsule A-S Medication Solutions

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

50 MG

adults and children 12 years	1 capsule
of age and over	
children 6 years to under 12	Ask a doctor, the proper dosage strength is not
years of age	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: 50090-3787

NDC: 50090-3787-0 30 CAPSULE in a BOTTLE

NDC: 50090-3787-3 20 CAPSULE in a BOTTLE, PLASTIC

Diphenhydramine Hydrochloride



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50090-3787(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			
# Hom Codo	Packago Docarintion	Marketing Start	Marketing End

#	item Code	гаскаде резсприон	Date	Date
	NDC:50090- 3787-0 30 in 1 BOTTLE; Type 0: Not a Combination Product 0		03/18/2019	
	NDC:50090- 3787-2	15 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2014	09/30/2021
-	NDC:50090- 24 in 1 BOTTLE, PLASTIC; Type 0: Not a 3787-1 Combination Product		11/28/2014	07/31/2021
4	NDC:50090- 3787-3	20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/28/2014	

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	01/02/2009	

Labeler - A-S Medication Solutions (830016429)

Establishment				
Name	Address	ID/FEI	Business Operations	
A-S Medication Solutions		830016429	RELABEL(50090-3787), REPACK(50090-3787)	

Revised: 12/2023 A-S Medication Solutions