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.

0835K- Major

Drug Facts

Active ingredient (in each capsule)
Diphenhydramine HCl 25 mg

Purpose
Antihistamine

Uses

 temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: runny nose sneezing itchy, watery eyes itching of the nose or throat

 to make a child sleepy

 with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have
 a breathing problem such as emphysema or chronic bronchitis

 glaucoma
 trouble urinating due to an enlarged 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 (1-800-222-1222).

Directions

 take every 4 to 6 hours, or as directed by a doctor

 do not take more than 6 doses in 24 hours

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

Other information

 store in a dry place at 15° – 30°C (59° – 86°F)

corn starch, D&C red #28, FD&C blue #1, FD&C red #40, gelatin, lactose monohydrate, magnesium stearate, sodium lauryl sulfate

Questions or comments?

1-800-616-2471

Distributed by: MAJOR® PHARMACEUTICALS, Indianapolis, IN 46268

Product of China. Manufactured and packaged in the USA using domestic and imported ingredients.

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl®.

To preserve quality and freshness, keep bottle tightly closed.

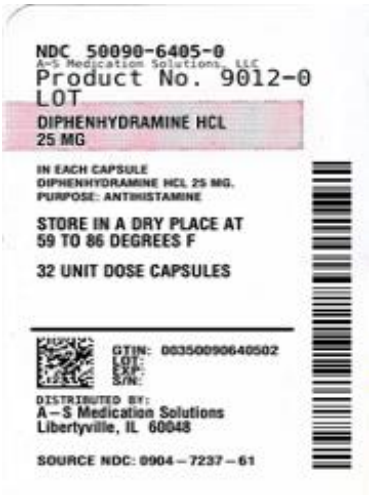
KEEP OUT OF REACH OF CHILDREN. DO NOT USE IF PRODUCT APPEARS TO BE TAMPERED WITH OR IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING.
DO NOT USE IF RED CAPSULE BAND IS BROKEN OR MISSING.

HOW SUPPLIED

Product: 50090-6405

NDC: 50090-6405-0 1 CAPSULE in a BLISTER PACK / 32 in a BOX, UNIT-DOSE

DIPHENHYDRAMINE HYDROCHLORIDE



DIPHENHYDRAMINE HYDROCHLORIDE

diphenhydramine hydrochloride capsule

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50090-6405(NDC:0904-7237)
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STARCH, CORN (UNII: O8232NY3SJ)	

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-6405-0	32 in 1 BOX, UNIT-DOSE	03/22/2023	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/14/2022	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-6405)

Revised: 3/2023 A-S Medication Solutions