

**ALLERGY RELIEF- diphenhydramine hcl capsule
McKesson (Sunmark)**

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 25 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms of the common cold:

- runny nose
- sneezing

temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

Warnings

Do not use

- 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

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

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, not more than 6 doses in 24 hours

adults and children 12 years of age and over	take 1 or 2 capsules
children 6 to under 12 years of age	take 1 capsule
children under 6 years of age	consult a doctor
children under 4 years of age	do not use

Other information

- store at controlled room temperature 15°-30°C (59°-86°F) in a dry place
- protect from light
- do not use if imprinted safety seal under cap is broken or missing
- do not use if red band around capsule is broken or missing

Inactive ingredients

D&C red #28, edible ink, FD&C blue #1, FD&C red #40, gelatin, lactose and starch.

Questions or comments?

Call toll free 1-877-753-3935

Principal Display Panel

Allergy Relief

Antihistamine

For the temporary relief of:

sneezing, itchy & watery eyes, runny nose & itchy throat

Diphenhydramine HCl 25 mg

Compare to Benadryl® Kapgels® Active Ingredient*

*This product is not manufactured or distributed by McNeil Consumer Healthcare, Division of McNeil-PPC, Inc., owner of the registered trademark Benadryl® Allergy Kapgels®

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Product Label



Diphenhydramine HCl 25 mg

ALLERGY RELIEF

diphenhydramine hcl capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-971
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: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	PINK (and white)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	CPC835
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-971-10	1 in 1 BOX	08/26/2011	12/31/2020
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	08/26/2011	12/31/2020

Labeler - McKesson (Sunmark) (177667227)

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