

**ALLERGY RELIEF ANTIHISTAMINE- diphenhydramine hcl tablet
Cardinal Health (Leader) 49781**

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 tablet)

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
- temporarily relieves these symptoms due to the common cold:
 - runny nose
 - sneezing

Warnings

Do not use

- 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
- do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	take 1 to 2 tablets
children 6 to under 12 years of age	take 1 tablet
children under 6 years of age	do not use this product in children under 6

Other information

- each tablet contains: **calcium 25 mg/tablet**
- store at room temperature 15°-30°C (59°-86°F)
- protect from light and moisture

Inactive ingredients

carnauba wax, colloidal silicon dioxide, croscarmellose sodium, D&C red #27 Aluminum Lake, dibasic calcium phosphate dihydrate, hypromellose, lecithin*, magnesium stearate, microcrystalline cellulose, polyethylene glycol (PEG) 400, polysorbate 80, polyvinyl alcohol*, purified water*, talc*, titanium dioxide

*contains one or more of these ingredients

Questions or comments?

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

Compare to Benadryl® Allergy ULTRATAB® active ingredient†

Allergy Tablets

Diphenhydramine HCl 25 mg

Antihistamine

For Allergy Relief

- Runny Nose • Sneezing
- Itchy Throat • Itchy, Watery Eyes

TABLETS

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

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

DISTRIBUTED BY: CARDINAL HEALTH

DUBLIN, OH 43017

Product Label



Leader Allergy Tablets

ALLERGY RELIEF ANTIHISTAMINE			
diphenhydramine hcl tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:4978 1-058
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
DIPHENHYDRAMINE HYDRO CHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)		DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
Inactive Ingredients			
Ingredient Name			Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
D&C RED NO. 27 (UNII: 2LRS185U6K)			
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
EGG PHOSPHOLIPIDS (UNII: 1Z74184RGV)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			

CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
WATER (UNII: 059QF0K00R)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	PINK	Score	no score
Shape	CAPSULE	Size	12mm
Flavor		Imprint Code	T;061;V;25;S4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49781-058-24	2 in 1 CARTON	09/28/2011	12/31/2020
1		12 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	part336	09/28/2011	12/31/2020

Labeler - Cardinal Health (Leader) 49781 (097537435)

Revised: 12/2018

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