ALLERGY RELIEF- diphenhydramine hydrochloride tablet TOP CARE (Topco Associates LLC)

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:
 - o runny nose
 - sneezing
 - itchy, watery eyes
 - itching of the nose or throat
- temporarily relieves these symptoms due to the common cold:
 - o 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 of 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	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

Other information

- each tablet contains: calcium 25 mg
- store between 20-25°C (68-77°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

Questions or comments?

Call toll free1-888-423-0139

Principal Display Panel

COMPLETE ALLERGY RELIEF

Allergy Relief Tablets

DIPHENHYDRAMINE HCl, 25 mg ANTIHISTAMINE

For allergy relief

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

COMPARE TO BENADRYL® ALLERGY active ingredient**

TABLETS

**This product is not manufactured or distributed by McNeil Consumer Healthcare, Distributor of Benadryl® Allergy.

DISTRIBUTED BY TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007

1-888-423-0139 ©TOPCO topcare@topco.com

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

^{*} contains one or more of these ingredients

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Product Label

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER Unit is torn, broken or shows any signs of tampering.

**This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl® Allergy.

Questions or comments?

*contains one or more of these ingredients

Inactive ingredients carnauba wax, colloidal allicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, dibasic calcium phosphate dihydrate, hypromellose, lecithin*, magnesium stearate, microcrystalline cellulose, polyetrylene glycol, polysorbate, polyvinyl alcohol*, punfled water*, talc*, titanium

- protect from light and moisture
- store between 20-25°C (68-77°F)
- esch tablet contains: calcium 25 mg

Other information

do not use	children under 6 years
take 1 tablet	children 6 to under 12 years
take 1 to 2 tablets	adults and children 12 years and over

- do not take more than 6 doses in 24 hours
- take every 4 to 6 hours, or as directed by a doctor

Directions

Drug Facts (continued)

(1-800-222-1222)

Keep out of reach of children. In case of overdose, get medical help or contact a Polson Control Center right away.

If **pregnant or breast-feeding**, ask a health professional before use.

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

When using this product

sedatives or tranquilizers.

Ask a doctor or pharmacist before use if you are taking

- trouble uninating due to an enlarged prostate gland
 - Aistocollis
- Ask a doctor before use if you have as breathing problem such as emphysema or chronic bronchitis

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

Do not use

Warnings

- Bulzaaus asou Auunu ■
- temporarily relieves these symptoms due to the common cold
 - itching of the nose or throat
 - runny nose sneezing itchy, watery eyes
 - upper respiratory allergies
- temporarily relieves these symptoms due to hay fever or other

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Drug Facts



Allergy Relief

DIPHENHYDRAMINE HCI 25 mg • ANTIHISTAMINE

NDC 36800-690-62

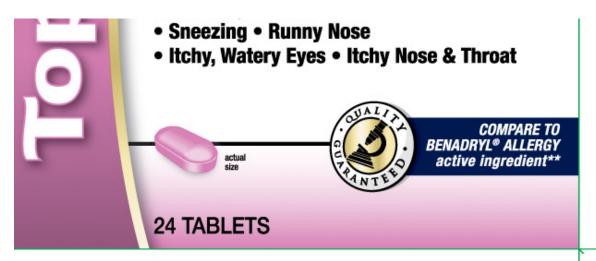


COMPLETE ALLERGY RELIEF

Allergy Relief Tablets

DIPHENHYDRAMINE HCI, 25 mg ANTIHISTAMINE

For Allergy Relief



Lot No.: Exp. Date:

DISTRIBUTED BY TOPCO ASSOCIATES LLC ELK GROVE VILLAGE, IL 60007 ©TOPCO PLV716 OUESTIONS? 1-888-423-0139 topcare@topco.com www.topcarebrand.com

This Top Care® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.



TopCare Allergy Relief Tablets

ALLERGY RELIEF

diphenhydramine hydrochloride tablet

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Product TypeHUMAN OTC DRUGItem Code (Source)NDC:36800-690

Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
DIPHENHYDRAMINE HYDRO CHLO RIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		

Inactive Ingredients			
Ingredient Name	Strength		
CARNAUBA WAX (UNII: R12CBM0EIZ)			
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)			
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)			
D&C RED NO. 27 (UNII: 2LRS185U6K)			
CALCIUM PHO SPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)			
HYPROMELLOSES (UNII: 3NXW29 V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POLYSORBATE 80 (UNII: 6 OZP39 ZG8 H)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			

TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
EGG PHO SPHO LIPIDS (UNII: 1Z74184RGV)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics				
Color	PINK	Score	no score	
Shape	CAPSULE	Size	12mm	
Flavor		Imprint Code	T61;V25;S4	
Contains				

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:36800-690- 36	3 in 1 CARTON	03/31/2013	12/30/2020			
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product					
2	NDC:36800-690- 62	24 in 1 CARTON	03/31/2013	12/30/2020			
2		1 in 1 BLISTER PACK; Type 0: Not a Combination Product					
3	NDC:36800-690- 67	48 in 1 CARTON	03/31/2013	12/30/2020			
3		1 in 1 BLISTER PACK; Type 0: Not a Combination Product					
4	NDC:36800-690- 78	1 in 1 BOX	03/31/2013	12/30/2020			
4		100 in 1 BOTTLE, PLASTIC; 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	03/31/2013	12/30/2020		

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 10/2019 TOP CARE (Topco Associates LLC)