ALLERGY RELIEF- diphenhydramine hcl 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:

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

temporarily relieves these symptoms of 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 operating machinery or driving a motor vehicle
- 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 and over	take 1 to 2 tablets
children 6 to under 12 years	take 1 tablet
children under 6 years	do not use

Other information

- each tablet contains: calcium 25mg
- 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, polysorbate, polyvinyl alcohol*, *purified water, *talc, and titanium dioxide

* Contains one or more of these ingredients

Questions or comments?

Call toll free 1-888-423-0139

Principal Display Panel

COMPARE TO BENADRYL® ALLERGY ACTIVE INGREDIENT**

Allergy Relief

DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE

RELIEF OF:

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

TABLETS

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

TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

DISTRIBUTED BY TOPCO ASSOCIATED LLC

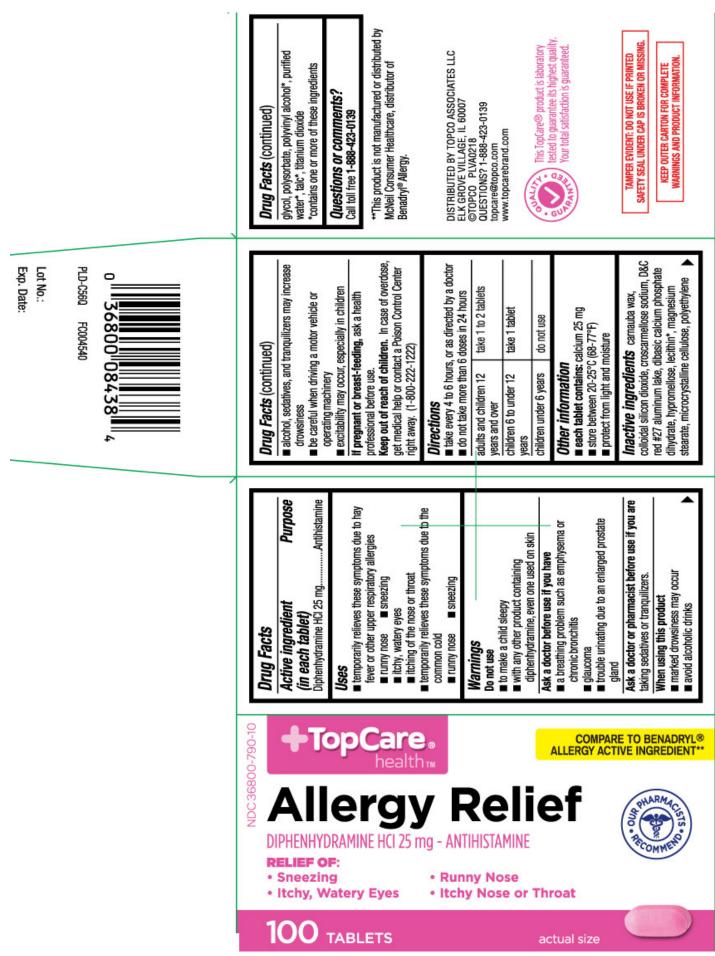
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Product Label



TOPCARE HEALTH Allergy Relief

ALLERGY RELIEF

diphenhydramine hcl tablet

Droduct Inform	ation							
Product Inform	ation							
Product Type		HUMAN OTC	DRUG	ltem Co	de (Source)	NDC:3680	0-790
Route of Administ	ration	ORAL						
Active Ingredie								-
	Ingredient Name Basis o				-	Strength		
DIPHENHYDRAMINE (DIPHENHYDRAMINE - U			I C2D6JAD40)			HYDRAMIN CHLORIDE	E	25 mg
Inactive Ingred	ients							
		-	ient Name				S	trength
CARNAUBA WAX (UN SILICON DIOXIDE (UI								
	-		48)					
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) D&C RED NO. 27 (UNII: 2LRS185U6K)								
CALCIUM PHOSPHAT		-	(UNII: 07TSZ	97GEP)				
HYPROMELLOSES (U								
EGG PHOSPHOLIPID	S (UNII: 1Z74	184RGV)						
MAGNESIUM STEARA	ATE (UNII: 70	097M6I30)						
CELLULOSE, MICRO	CRYSTALLIN	E (UNII: OP1R	32D61U)					
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)								
POLYSORBATE 80 (U	JNII: 60ZP392	ZG8H)						
POLYVINYL ALCOHO		FIED (UNII: 53	32B59J990)					
WATER (UNII: 059QF0								
TALC (UNII: 7SEV7J4R	1U)							
	1U)	'2JP)						
TALC (UNII: 7SEV7J4R	1U)	'2JP)						
TALC (UNII: 7SEV7J4R	1U) UNII: 15FIX9V	'2JP)						
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (1U) UNII: 15FIX9V	2JP)	Score			no score		
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (Product Charac	1U) UNII: 15FIX9V teristics		Score Size			no score 11mm		
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (Product Charac Color	1U) UNII: 15FIX9V teristics pink			de			5;54	
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (Product Charac Color Shape	1U) UNII: 15FIX9V teristics pink		Size	de		11mm	5;54	
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (Product Charac Color Shape Flavor	1U) UNII: 15FIX9V teristics pink		Size	de		11mm	5;\$4	
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (Product Charac Color Shape Flavor Contains	1U) UNII: 15FIX9V teristics pink		Size	de		11mm	5;\$4	
TALC (UNII: 7SEV7J4R: TITANIUM DIOXIDE (Product Charac Color Shape Flavor Contains Packaging	1U) UNII: 15FIX9V teristics pink CAPSUL	E	Size Imprint Co		Marketing	11mm T;061;V;2	Market	ing End
TALC (UNII: 7SEV7J4R TITANIUM DIOXIDE (Product Charac Color Shape Flavor Contains Packaging # Item Code	1U) UNII: 15FIX9V teristics pink CAPSUL		Size Imprint Co		Marketing Date	11mm T;061;V;2	Market	ing End
TITANIUM DIOXIDE Product Charac Color Shape Flavor Contains Product Charac Pro	1U) UNII: 15FIX9V teristics pink CAPSUL	E ckage Des	Size Imprint Co	02/		11mm T;061;V;2	Market	

	00 in 1 BOTTLE; Type 0: Not a Combination Product	02/28/2018				
Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
OTC monograph final	part341	02/28/2018				

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

Revised: 12/2022

TOP CARE (Topco Associates LLC)