ALLERGY RELIEF- diphenhydramine hydrochloride tablet, coated 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.

TCR - 1090 - 2019-1016

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

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- 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 times in 24 hours

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

Other information

- each tablet contains: calcium 45 mg
- store between 20-25°C (68-77°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, dibasic calcium phosphate, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 36800-909-01

TopCare® Health™

Compare to Benadryl® Allergy Tablets Active Ingredient*

Allergy Relief

Diphenhydramine HCl 25 mg

Antihistamine

Relief of:

Sneezing

Itchy, watery eyes

Runny Nose

Itchy Throat



Allergy Relief

24 TABLETS

DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE

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

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
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OUESTIONS 7 - 888-423-0139
topcase@topco.com
www.topcarebrand.com

Scan here for more information or call 1-888-423-0139

GUALITY GUARANTEED



bojketnylene glycol, titanium dioxide calcium phosphate, FD&C yellow #6 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide, croscarmellose sodium, D&C red #27 aluminum lake, dibasic Inactive ingredients ■ retain carton for complete product information ■ store between 20-25°C (68-77°F) ■ each tablet contains: calcium 45 mg Other information esu ton ob children under 6 years children 6 to under 12 years adults and children 12 years and over 1 to 2 tablets ■ do not take more than 6 times in 24 hours ■ take every 4 to 6 hours, or as directed by a doctor Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away If pregnant or breast-feeding, ask a health professional before use. be careful when driving a motor vehicle or operating machinery alcohol, sedatives, and tranquilizers may increase drowsiness Myeu najud tuja broduct marked drowsiness may occur ■ SAOIQ SICOUOJIC QUUKS Yak a doctor or pharmacist before use it you are taking sedatives or tranquilizers a breathing problem such as emphysema or chronic bronchitis trouble urinating due to an enlarged prostate gland ■ djancoma Ask a doctor before use if you have ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one used on skin ■ trumy nose temporarily relieves these symptoms due to the common cold: itching of the nose or throat itchy, watery eyes 6uizəəus ■ temporarily relieves these symptoms due to hay fever or other upper respiratory allergies: Antihistamine Diphenhydramine HCl 25 mg... Active ingredient (in each tablet) Purpose Drug Facts



Allergy Relief

24 TABLETS

DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE

+TopCare health

COMPARE TO BENADRYL® ALLERGY TABLETS ACTIVE INGREDIENT*

200

Allergy Relief

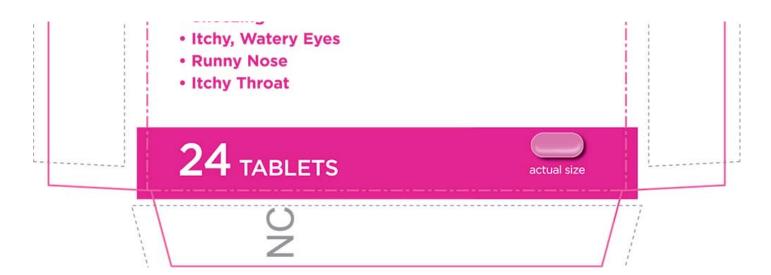
DIPHENHYDRAMINE HCI 25 mg - ANTIHISTAMINE

RELIEF OF:

Sneezing

 $\stackrel{\circ}{\geq}$

-109001TCR



ALLERGY RELIEF

diphenhydramine hydrochloride tablet, coated

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:36800-909

Route of Administration ORAL

Active Ingredient/Active Moiety

Active migredient/Active Molecy			
Ingredient Name	Basis of Strength	Strength	
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40)	DIPHENHYDRAMINE	25 mg	

Inactive Ingredients		
Ingredient Name	Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)		
D&C RED NO. 27 (UNII: 2LRS185U6K)		
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: L11K75P92J)		
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		
ALUMINUM OXIDE (UNII: I MI2606933)		

Product Characteristics				
Color	pink	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	25;052	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800- 909-01	2 in 1 CARTON	08/30/2011	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:36800- 909-02	4 in 1 CARTON	08/30/2011	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:36800- 909-03	1 in 1 CARTON	08/30/2011	04/30/2024
3		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:36800- 909-05	400 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/30/2011	07/31/2022

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/30/2011	

Labeler - TopCo Associates LLC (006935977)

Revised: 11/2022 TopCo Associates LLC