

DIPHENHYDRAMINE- diphenhydramine hydrochloride tablet, coated
AAA Pharmaceutical, Inc.

RES - 1090 - 2019-1012

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 with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

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
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

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.

Directions

- take every 4 to 6 hours
- do not exceed 6 doses in 24 hours

adults and children 12 years of age and over	25 mg to 50 mg (1 to 2 tablets)
children 6 to under 12 years of age	12.5 mg * to 25 mg (1 tablet)
children under 6 years of age	ask a doctor

* 12.5 mg dosage strength is not available in this package. Do not attempt to break tablets.

Other information

- each tablet contains: **calcium 45 mg**
- store at room temperature 15°-30°C (59°-86°F)
- retain carton for complete product information

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, D&C red #27, dibasic calcium phosphate, FD&C yellow #6, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

PRINCIPAL DISPLAY PANEL

RESTORE U

NDC 57344-090-02

†COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL® ALLERGY ULTRATABS®

Allergy Relief

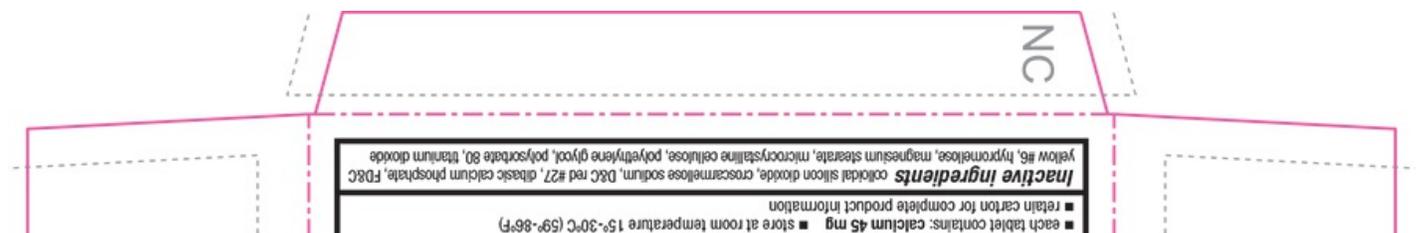
Antihistamine

Diphenhydramine HCl

Easy To Swallow

Relieves: • Sneezing • Runny Nose
• Itchy, Watery Eyes • Itchy Throat

48 TABLETS



Drug Facts	Active Ingredient (in each tablet) Diphenhydramine HCl 25 mg.....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 with any other product containing diphenhydramine, even one used on skin ■ Ask a doctor before use if you have ■ glaucoma ■ trouble urinating due to an enlarged prostate gland ■ a breathing problem such as emphysema or chronic bronchitis ■ Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ marked drowsiness may occur ■ avoid alcoholic drinks ■ When using this product ■ be careful when driving a motor vehicle or operating machinery ■ 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.	
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Other Information	

NC

NC

RESTORE^u **Allergy Relief**
Antihistamine
Diphenhydramine HCl
48 TABLETS
Easy To Swallow

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Relieves:

- Sneezing
- Itchy, Watery Eyes
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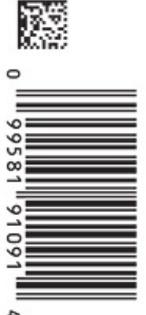
NDC 57344-090-02
*COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL[®] ALLERGY ULTRATABS[®]

F109002RES_R0

Distributed by:
AAA Pharmaceutical, Inc.
157-160 W. Jefferson St.
Paulishoro, NJ 09066

*This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Benadryl[®] Allergy Ultratabs[®].

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN



RESTORE^u **Allergy Relief**
Antihistamine
Diphenhydramine HCl
48 TABLETS
Easy To Swallow

DIPHENHYDRAMINE

diphenhydramine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-090
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
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)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:57344-090-02	4 in 1 CARTON	04/13/2012	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:57344-090-03	1 in 1 CARTON	11/27/2017	
2		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 Drug	M012	04/13/2012	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 12/2024

AAA Pharmaceutical, Inc.