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

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.

Diphenhydramine Tablets

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

Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048

PRINCIPAL DISPLAY PANEL - 48 Tablet Carton

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


NC
NC
NC
Drug Facts
Active ingredient (in each tablet)
Purpose
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
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 #5, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide
RESTORE u
Allergy Relief
Antihistamine
Diphenhydramine HCl
Easy To Swallow
48 TABLETS
RESTORE u
NDC 57344-0900-02
†COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL® ALLERGY ULTRATABS®
Allergy Relief
Antihistamine
Diphenhydramine HCl
Relieves: • Sneezing • Runny Nose • Itchy, Watery Eyes • Itchy Throat
Easy To Swallow
48 TABLETS
RESTORE u
Allergy
0 99581 91091 4
F1090028RES_R1
Distributed by:
AAA Pharmaceutical, Inc.
681 Main Street
Lumberton, NJ 08048
†This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Benadryl® Allergy Ultratabs®.
DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

DIPHENHYDRAMINE

diphenhydramine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:57344-090
Route of Administration	ORAL	**DEA Schedule**	

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DIPHENHYDRAMINE HYDROCHLORIDE (DIPHENHYDRAMINE)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients	
Ingredient Name	**Strength**
SILICON DIOXIDE	
CROSCARMELLOSE SODIUM	
D&C RED NO. 27	
CALCIUM PHOSPHATE, DIBASIC, ANHYDROUS	
FD&C YELLOW NO. 6	
HYPROMELLOSES	
MAGNESIUM STEARATE	
CELLULOSE, MICROCRYSTALLINE	
POLYETHYLENE GLYCOLS	
POLYSORBATE 80	
TITANIUM DIOXIDE	

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:57344-090-01	2 in 1 CARTON		
1		12 in 1 BLISTER PACK		
2	NDC:57344-090-02	4 in 1 CARTON		
2		12 in 1 BLISTER PACK		
3	NDC:57344-090-03	1 in 1 CARTON		

3		100 in 1 BOTTLE, PLASTIC		
4	NDC:57344-090-05	400 in 1 BOTTLE, PLASTIC		
5	NDC:57344-090-06	2 in 1 CARTON		
5		100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	12/22/2012	

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 12/2012 AAA Pharmaceutical, Inc.