DIPHENHYDRAMINE HCL- diphenhydramine hcl tablet, coated RedPharm Drug, 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 25mg tabs

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
 - itchy, watery eyes
 - sneezing
 - 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

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers.

When using this product

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness

- avoid alcoholic beverages
- use caution 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 (1-800-222-1222) right away

Directions

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

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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 30 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- use by expiration date on package

Inactive ingredients

corn starch, D&C red #27 aluminum lake, dicalcium phosphate, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments? (800) 645-2158

Principal display panel

Rugby ®

NDC 0536-1214-29

COMPARE TO THE ACTIVE INGREDIENT IN BENADRYL [®] ALLERGY ULTRATAB [®] TABLETS*

Diphenhydramine HCI, 25 mg

Antihistamine Allergy Relief

Relieves Sneezing, Runny Nose, Itchy throat & Itchy, Watery Eyes

100 TABLETS

Actual Size

Easy to Swallow

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

*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl® Allergy ULTRATAB® Tablets.

50844 ORG101632912

Distributed by: Rugby Laboratories, 17177 N Laurel Park Dr., Suite 233, Livonia, MI 48152

www.rugbylaboratories.com

Rev.02/19 R-17 Re-order No. 370672

Drug Facts (continued sedatives or tranquilizers. Ask a doctor or pharmacist before use if you are taking When using this product alcohol, sedatives, and tranquilizers may increase marked drowsiness may occur

use caution when driving a motor vehicle or operating avoid alcoholic beverages

excitability may occur, especially in children

Keep out of reach of children. In case of overdose, get pregnant or breast-feeding, ask a health professional

medical help or contact a Poison Control Center 1-800-222-1222) right away.

■ 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

1 to 2 tablets

1 tablet do not use

Directions

Do not use ■ to make a child sleepy ■ with any other product containing diphenhydramine, even one Ask a doctor before use if you have

used on skin

a breathing problem such as emphysema or chronic bronchitis

difficulty in urination due to enlargement of the prostate gland 'This product is not manufactured or distributed by Johnson & Johnsor owner of the registered trademark Benadryl® Allergy ULTRATAB® Tablets Distributed by: Rugby Laboratories, 17177 N Laurel Park Dr., Suite 233, Livonia. MI 48152

ORG101632912

MORE DRUG FACTS

PEEL HERE FOR

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

Easy to Swallow

Rx Only



Rugby

NDC 0536-1214-29

Relieves Sneezing,

Runny Nose, Itchy Throat & Itchy, Watery Eyes **100 TABLETS**

Diphenhydramine

HCI, 25 mg

Antihistamine

Allergy Relief

(21)100000000000048 (01)00367296142679 (10)120782X1 (17)220630

NDC: 67296-1426-7 DIPHENHYDRAMINE HCL 25MG 24 Tablets

120782X1 Lot:

■ each tablet contains: calcium 30 mg

Other information

children under 6 years children 6 to under 12 years

■ store at 25°C (77°F); excursions permitted between

use by expiration date on package

15°-30°C (59°-86°F)

protect from moisture

Purpose

Active ingredient (in each tablet,

Orua Facts

Diphenhydramine HCI 25 mg

Antihistamine

temporarily relieves these symptoms due to hay fever or other

temporarily relieves these symptoms due to the common

■ runny nose ■ sneezing

itching of the nose or throat

itchy, watery eyes

runny nose

sneezing

upper respiratory allergies

nicrocrystalline cellulose, polyethylene glycol, polyviny Inactive ingredients com starch, D&C red #27

luestions or comments?

(800) 645-2158

STOP PEELING

lumınum lake, dıcalcıum phosphate, magnesium stearate

Exp: 06/22

Usual adult dosage: See package insert

Store at controlled room temperature: 20-25 C (68-77 F)

Rugby Laboratories Mfg: Livonia MI 48152

0536-1214-29

Dist. by: Redpharm Drug Eden Prairie, MN 55344

SIN 13466



DIPHENHYDRAMINE HCL

diphenhydramine hcl tablet, coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67296-1426(NDC:0536-1214)	
Pouto 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			
STARCH, CORN (UNII: O8232NY3SJ)				
D&C RED NO. 27 (UNII: 2LRS185U6K)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)				

Product Characteristics			
Color	pink	Score	no score
Shape	OVAL	Size	11mm
Flavor		Imprint Code	44;329
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67296- 1426-7	24 in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	03/28/2019	

Establishment			
Name	Address	ID/FEI	Business Operations
EPM Packaging, Inc.		079124340	repack(67296-1426), label(67296-1426)

Revised: 3/2021 RedPharm Drug, Inc.