WAL-DRYL PE ALLERGY AND SINUS- diphenhydramine hcl, phenylephrine hcl tablet, film coated

Walgreen Company

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.

Walgreens 44-485-Delisted

Active ingredients (in each tablet)

Diphenhydramine HCl 25 mg Phenylephrine HCl 10 mg

Purpose

Antihistamine Nasal decongestant

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
 - runny nose
 - sneezing
 - nasal congestion
 - itching of the nose or throat
 - itchy, watery eyes
- temporarily relieves these symptoms due to the common cold:
 - nasal congestion
 - runny nose
 - sneezing
- temporarily relieves sins congestion and pressure

Warnings

Do not use

- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.
- with any other product containing diphenhydramine, even one used on skin

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- diabetes
- thyroid disease
- heart disease
- glaucoma
- high blood pressure
- 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

- do not exceed recommended dosage
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- symptoms do not improve within 7 days or are accompanied by fever
- nervousness, dizziness, or sleeplessness occur

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

- adults and children 12 years and over
 - take 1 tablet every 4 hours
 - do not take more than 6 tablets in 24 hours
- children under 12 years:do not use

Other information

- each tablet contains: calcium 25 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal display panel

Well at

Walgreens

WALGREENS PHARMACIST RECOMMENDED

NDC 0363-4850-08

Wal-Dryl PE®

PE Allergy & Sinus

Diphenhydramine HCl 25 mg / Antihistamine Phenylephrine HCl 10 mg / Nasal Decongestant

• Relief of sinus congestion & pressure, runny nose, sneezing, itchy throat & itchy, watery eyes

24 COATED MINI TABS

Actual Size

Compare to Benadryl® Allergy Plus Congestion active ingredients‡‡

EASY-TO-SWALLOW MINI TABS • PSEUDOEPHEDRINE FREE

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

DOES NOT CONTAIN GLUTEN

‡Walgreens Pharmacist Survey Study, November 2016.

‡‡This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl® Allergy Plus Congestion.

DISTRIBUTED BY: WALGREEN CO. 200 WILMOT RD., DEERFIELD, IL 60015 Walgreens 100% SATISFACTION GUARANTEED walgreens.com © 2017 Walgreen Co.

50844 REV1017B48508

Exp Date Only

1-800-456-9391 Guestions or comments?

titanium dioxide, triacetin polyethylene glycol, silicon dioxide, stearic acid, microcrystalline cellulose, polydextrose,

Drug Facts (continued)

aluminum lake, hypromellose, magnesium stearate,

dibasic calcium phosphate dihydrate, FD&C blue #1 Inactive ingredients croscarmellose sodium,

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

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE

IS OPENED OR BLISTER IS TORN OR BROKEN

■ do not take more than 6 tablets in 24 hours

medical help or contact a Poison Control Center

■ nervousness, dizziness, or sleeplessness occur

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excuspility may occur, especially in children

■ do not exceed recommended dosage

Keep out of reach of children. In case of overdose, get

If pregnant or breast-feeding, ask a health professional

use caution when driving a motor vehicle or operating drowsiness a avoid alcoholic beverages sicohol, sedatives, and tranquilizers may increase

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adults and children 12 years and over

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(1-800-222-1222) right away.

accompanied by fever

Stop use and ask a doctor if

■ marked drowsiness may occur

When using this product

Drug Facts (continued)

■ see end flap for expiration date and lot number

12,-30,C (26,-89,E)

Other information

Directions

machinery

This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Benadryl Allergy Plus Congestion. Walgreens Pharmacist Survey Study, November 2016. DOES NOT CONTAIN GLUTEN

OR SHOWS ANY SIGNS OF TAMPERING OPENED OR IF BLISTER UNIT IS TORN, BROKEN TAMPER EVIDENT: DO NOT USE IF PACKAGE IS

sedatives or tranquilizers.

Ask a doctor or pharmacist before use if you are taking

SATISFACTION
GUARANTEED

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REV1017B48508

TRIBUTED BY: WALGREEN CO.

- a breathing problem such as emphysema or chronic ■ disncoms ■ pidp plood bressure ■ heart disease ■ thyroid disease prostate gland a diabetes
 - quiticulty in unination due to enlargement of the Ask a doctor before use if you have
 - even one used on skin
- with any other product containing diphenhydramine, product.

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if you are now taking a prescription monoamine

Do not use Warnings

- temporarily relieves sinus congestion and pressure
 - Buizeeus ■ runny nose
 - common cold: mussal congestion
- temporanily relieves these symptoms due to the itching of the nose or throat
 itchy, watery eyes ■ usasi congestion Burgaaus ■ asou Auunu ■
- or other upper respiratory allergies: femboranily relieves these symptoms due to hay lever

Nasal decongestant Phenylephrine HCI 10 mg Diphenhydramine HCI 25 mg Antihistamine

(in each tablet) Active ingredients

Drug Facts

Purpose

COMPLETE PRODUCT INFORMATION KEEP OUTER PACKAGE FOR

Well at

WALGREENS PHARMACIST RECOMMENDED^a

Wal-Dryl PE°

PE Allergy & Sinus

B-2201-485-08-R

REV1017B48508

WALGREENS PHARMACIST RECOMMENDED*

Wal-Dryl PE[®]

PE) Allergy & Sinus

Diphenhydramine HCI 25 mg / Antihistamine Phenylephrine HCI 10 mg / Nasal Decongestant



Walgreens 44-485

WAL-DRYL PE ALLERGY AND SINUS

diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4850		
Route of Administration	ORAL				

	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
	$\label{eq:diphenhydramine} \textbf{DIPHENHYDRAMINE HYDRO CHLO RIDE} \ (\text{UNII: } \text{TC2D6JAD40} \) \ (\text{DIPHENHYDRAMINE -UNII:8GTS82S83M})$	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		
	PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg		

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Product Characteristics				
Color	BLUE	Score	no score	
Shape	OVAL	Size	11mm	
Flavor		Imprint Code	44;485	
Contains				

Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:0363-4850- 08	2 in 1 CARTON	08/10/2005	12/06/2021	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
OTC MONOGRAPH FINAL	part341	08/10/2005	12/06/2021		

Labeler - Walgreen Company (008965063)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	MANUFACTURE(0363-4850)	

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	PACK(0363-4850)	

Revised: 12/2019 Walgreen Company