ALLERGY RELIEF- acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated Walgreen Company

Walgreens 44-543 AR

Active ingredients (in each caplet)

Acetaminophen 325 mg Diphenhydramine HCl 25 mg Phenylephrine HCl 5 mg

Purpose

Pain reliever Antihistamine Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies:
 - headache
 - nasal congestion
 - sneezing
 - runny nose
 - sinus congestion and pressure
 - itchy, watery eyes
 - itching of the nose or throat
 - minor aches and pains

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- with any other product containing diphenhydramine, even one used on skin
- 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- glaucoma
- heart disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- liver disease
- thyroid disease
- diabetes

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- 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
- use caution when driving a motor vehicle or operating machinery
- avoid alcoholic beverages

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- do not take more than directed
- adults and children 12 years and over
 - take 2 caplets every 4 hours
 - do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

- see end flap for expiration date and lot number
- 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)

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, FD&C blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-800-426-9391

Principal display panel

Walgreens

WALGREENS PHARMACIST RECOMMENDED[†]

NDC 0363-5430-09

Allergy Relief SEVERE ALLERGY & SINUS HEADACHE ACETAMINOPHEN / PAIN RELIEVER DIPHENHYDRAMINE HCI / ANTIHISTAMINE PHENYLEPHRINE HCI / NASAL DECONGESTANT

Maximum Strength

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

20 CAPLETS

ACTUAL SIZE

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com

©2021 Walgreen Co.

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

50844 ORG091854309

[†]Our pharmacists recommend the Walgreens brand.

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

TEM 555466

W00000-0000-0

W30RG0821-F2

C Questions or comments? 1-800-426-9391

see end flap for expiration date and lot number

■ do not take more than 10 caplets in 24 hours

Directions a do not take more than directed

cyrigten even if you do not nodes any signs or symptoms.

Prompt medical attention is cribical for adults as well as for

get medical help or contact a Poison Control Center right away.

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

If pregnant or breast-feeding, ask a health professional before

■ beju or nasal congestion gets worse or lasts more than 7 days

■ redness or swelling is present ■ new symptoms occur

■ tever gets worse or lasts more than 3 days

Stop use and ask a doctor if

■ nervousness, dizziness, or sleeplessness occur

children under 12 years: ask a doctor

squits and children 12 years and over

■ take 2 caplets every 4 hours

steanc acid, tranium dioxide, triacetin polydextrose, polyethylene glycol, povidone, silicon dloxide, hypromellose, magnesium stearate, microcrystalline cellulose, sodium, crospovidone, FD&C blue #1 aluminum lake,

Drug Facts (continued)

nottem total 19410

INACTIVE INGIECIENTS com starch, croscarmellose

- store at 25°C (77°F); excursions permitted between 15°-30°C OPENED OR BLISTER IS TORN OR BROKEN
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS

Drug Facts (continued)

ot its ingredients



DATE ONLY

EXP I

Ø

FOT 9

PRINT

Our pharmacists recommend the Walgreens brand.

DISTRIBUTED BY: WALGREEN CO.
200 WILMOT RD., DEERFIELD, IL 60015
100% SATISFACTION GUARANTEED
walgreens.com
©2021 Walgreen Co.

ORG091854309

50844

■ if you have ever had an allergic reaction to this product or any

pharmacist before taking this product. prescription drug contains an MAOI, ask a doctor or after stopping the MAOI drug. If you do not know if your emotional conditions, or Parkinson's disease), or for 2 weeks

inhibitor (MAOI) (certain drugs for depression, psychiatric or ■ if you are now taking a prescription monoamine oxidase upys uo pasn

 with any other product containing diphenhydramine, even one scetsminophen, ask a doctor or pharmacist.

nonprescription). If you are not sure whether a drug contains wgp suk ogjet grad containing scetaminophen (prescription or

o not use

If a skin reaction occurs, stop use and seek medical help right

■ skin reddening ■ blisters ■ rash Symptoms may include:

Allergy alert: Acetaminophen may cause severe skin reactions. 3 or more alcoholic drinks every day while using this product

■ with other drugs containing acetaminophen

■ more than 4,000 mg of acetaminophen in 24 hours Inst damage may occur if you take

Liver warning: This product contains acetaminophen. Severe

Spainie W

■ unuou scues suo barus

 Itching of the nose or throat saéa Áugren, 'Augu suns coudeanou sun bissanie Bussal congesting ■ sneezing asou Yunun m

other upper respiratory allergies: исведения sasn temporarily relieves these symptoms of hay fever or

Phenylephine HCl 5 mg Nasal decongestant animistaindnA. Diphenhydramine HCl 25 mg Pain reliever Acetaminophen 325 mg

Purpose Active ingredients (in each caplet)

COMPLETE PRODUCT INFORMATIO

Drug Facts

machinery avoid alcoholic beverages nee cantion when driwing a motor vehicle or operating alcohol, sedatives, and tranquilizers may increase drowsiness ■ INAINSO DIOWSINESS MAY OCCUIT excitability may occur, especially in children ■ do not exceed recommended dosage When using this product taking sedatives or tranquilizers m taking the blood thinning drug warrann Ask a doctor or pharmacist betore use if you are pronchitis milver disease mthyroid disease s preathing problem such as emphysema or chronic difficulty in urination due to enlargement of the prostate gland ■ glaucoma ■ heart disease ■ high blood pressure Ask a doctor before use it you have

Drug Facts (continued)

Walgreens (

Allergy Relief

NDC 0363-5430-09

Walgreens 🖟

ergy Relief

SEVERE ALLERGY & SINUS HEADACHE

ACETAMINOPHEN / PAIN RELIEVER DIPHENHYDRAMINE HCI / ANTIHISTAMINE PHENYLEPHRINE HCI / NASAL DECONGESTANT

Maximum Strength

B-2201-543-09-HR ORG091854309

Walgreens 44-543 ORG0918

ALLERGY RELIEF

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-5430	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg		
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients				
Ingredient Name	Strength			
STARCH, CORN (UNII: O8232NY3SJ)				
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)				
CROSPOVIDONE (UNII: 2S7830E561)				
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				
POLYDEXTROSE (UNII: VH2XOU12IE)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
TRIACETIN (UNII: XHX3C3X673)				

Product Characteristics				
Color	blue	Score	no score	

Shape	OVAL	Size	16mm
Flavor		Imprint Code	44;543
Contains			

F	Packaging						
#	t Item Code Package Description		Marketing Start Date	Marketing End Date			
1	NDC:0363- 5430-09	2 in 1 CARTON	11/04/2021				
1	L	10 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 Drug	M012	11/04/2021		

Labeler - Walgreen Company (008965063)

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867837	pack(0363-5430)	

Establishment				
Name	Address	ID/FEI	Business Operations	
LNK International, Inc.		832867894	manufacture(0363-5430)	

Revised: 11/2023 Walgreen Company