## SEVERE ALLERGY PLUS SINUS HEADACHE- acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated Wal-Mart Stores Inc

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**Equate 44-543** 

#### 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?

1-888-287-1915

#### **Principal Display Panel**

equate™

NDC 49035-543-09

## **Quality Guaranteed**

Maximum Strength

**Severe Allergy** 

Plus Sinus Headache

Acetaminophen, Diphenhydramine HCl,

Phenylephrine HCl

Pain Reliever/Antihistamine/Nasal Decongestant

#### Relieves:

- Sinus headache
- Sinus congestion
- Sinus pressure
- Sneezing
- Runny nose
- Itchy throat
- Itchy, watery eyes

## 20

**CAPLETS** 

## **Actual Size**

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

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

50844 REV0918G54309

Satisfaction guaranteed – Or we'll replace it or give you your money back. For questions or comments please call **1-888-287-1915.** 



Inactive ingredients corn starch, croscarmellose

**Drug Facts** (continued)

REV0918G54309

comments please 1-888-287-1915.

AR 72716

Or we'll replace it or give Satisfaction guaranteed you your money back or questions or

UU CUIONS OF COMMENTS? 1-888-287-1915

stearic acid, titanium dioxide, triacetin

## *eauate*™ Severe Allergy Plus Sinus Headache

KEEP OUTER PACKAGE FOR

Acetaminophen, Diphenhydramine HCl, Phenylephrine HCI

NDC 49035-543-09

Drug Facts



Quality Guaranteed

**Maximum Strength** 

# Severe Allergy Plus Sinus Headache

Acetaminophen, Diphenhydramine HCI, Phenylephrine HCI



**Equate 44-543** 

## SEVERE ALLERGY PLUS SINUS HEADACHE

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49035-543
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg		
<b>DIPHENHYDRAMINE HYDROCHLORIDE</b> (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, UNSPECIFIED (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	I	Imprint Code	44;543
Contains			

P	Packaging					
#	# Item Code Package Description		Marketing Start Date	Marketing End Date		
1	NDC:49035- 543-41	10 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/27/2007			
2	NDC:49035- 543-09	2 in 1 CARTON	06/27/2007			
2		10 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information				
Marketing Category	Application Number or Monograph Marketing Start Marketing End Citation Date Date			
OTC Monograph Drug	M012	06/27/2007		

## Labeler - Wal-Mart Stores Inc (051957769)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867837	pack(49035-543)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(49035-543)

Revised: 10/2023 Wal-Mart Stores Inc