#### SEVERE ALLERGY AND SINUS HEADACHE MAXIMUM STRENGTHacetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated CVS Pharmacy

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#### CVS 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?**

1-800-426-9391

# Principal Display Panel

♥ CVS Health™

Caplets

MAXIMUM STRENGTH Severe Allergy & Sinus Headache ACETAMINOPHEN, DIPHENHYDRAMINE HCI PHENYLEPHRINE HCI

Pain reliever, Antihistamine & Nasal decongestant

For Allergy Plus Sinus Pain & Pressure Relief of: Sneezing, Runny nose, Sinus headache, Sinus congestion, Sinus pain & pressure, Itchy, watery eyes

#### **20 CAPLETS**

Capsule-Shaped Tablets

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: CVS Pharmacy, Inc.

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**CVS**®Quality Money Back Guarantee

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# ♦CVSHealth



Severe Allergy & Sinus Headache

CVSHealth

#### Caplets

Caplets

MAXIMUM STRENGTH Severe Allergy & Sinus Headache ACETAMINOPHEN, DIPHENHYDRAMINE HOI

PHENYLEPHRINE HCI Pain reliever, Antihistamine & Nasal decongestant



CVS 44-543

#### SEVERE ALLERGY AND SINUS HEADACHE MAXIMUM STRENGTH acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated Product Information **Product Type** HUMAN OTC DRUG Item Code (Source) NDC:59779-543 ORAL **Route of Administration Active Ingredient/Active Moiety** Ingredient Name **Basis of Strength** Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D) ACETAMINOPHEN 325 mg DIPHENHYDRAMINE DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) 25 ma (DIPHENHYDRAMINE - UNII:8GTS82S83M) HYDROCHLORIDE PHENYLEPHRINE PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -5 mg UNII:1WS297W6MV) **HYDROCHLORIDE Inactive Ingredients Ingredient Name** Strength STARCH, CORN (UNII: 08232NY3SJ) 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: 3WQ0SDW1A) POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) SILICON DIOXIDE (UNII: ETI7Z6XBU4) STEARIC ACID (UNII: 4ELV7Z65AP) TITANIUM DIOXIDE (UNII: 15FIX9V2JP) TRIACETIN (UNII: XHX3C3X673) **Product Characteristics** Color blue Score no score

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отс	C Monograph Drug	M012			06/27/2007		

# Labeler - CVS Pharmacy (062312574)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
LNK International, Inc.		832867837	pack(59779-543)	

# Establishment

Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(59779-543)

Revised: 2/2024

**CVS** Pharmacy