

**SEVERE ALLERGY AND SINUS HEADACHE MAXIMUM STRENGTH-
acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated
CVS Pharmacy**

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 HCl
PHENYLEPHRINE HCl**

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**

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One CVS Drive, Woonsocket, RI 02895

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Caplets

MAXIMUM STRENGTH

Severe Allergy & Sinus Headache

ACETAMINOPHEN, DIPHENHYDRAMINE HCl, PHENYLEPHRINE HCl

B-0231-543-09-H
REV0918054309



Caplets

MAXIMUM STRENGTH

Severe Allergy & Sinus Headache

ACETAMINOPHEN, DIPHENHYDRAMINE HCl
PHENYLEPHRINE HCl

Pain reliever, Antihistamine & Nasal decongestant

Drug Facts

KEEP OUT OF REACH OF CHILDREN. COMPLETE PRODUCT INFORMATION

Purpose
Acetaminophen 325 mg.....Pain reliever
Diphenhydramine HCl 25 mg.....Antihistamine
Phenylephrine HCl 5 mg.....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 ■ 3 or more alcoholic drinks every day while using this product ■ with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ rash ■ skin redness ■ blisters ■ 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.

Drug Facts (continued)

Ask a doctor before use if you have ■ high blood pressure ■ glaucoma ■ heart disease ■ taking blood thinning drug warfarin ■ taking sedatives or tranquilizers ■ taking this product when using this product

When using this product ■ do not exceed recommended dosage ■ do not take more than 7 days ■ pain or nasal congestion gets worse or lasts more than 7 days ■ nervousness, dizziness, or sleeplessness occur ■ 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
■ TAMPER EVIDENT: DO NOT USE IF OUTER PACK AGE IS OPENED OR BLISTER IS TORN OR BROKEN

Drug Facts (continued)
hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions or comments?
1-800-426-9391

Inactive ingredients
corn starch, croscarmellose sodium, croscopolone, FD&C blue #1 aluminum lake, (59-88 F) ■ store at 25°C (77°F); excursions permitted between 15°-30°C

■ see end flap for expiration date and lot number

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no print / no varnish area
-lot no. & exp. date-

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



#343025-PE

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

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
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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: M28OL1HH48)	
CROSPVIDONE, 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)	
TRACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue	Score	no score
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Shape	OVAL	Size	16mm
Flavor		Imprint Code	44;543
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-543-09	2 in 1 CARTON	06/27/2007	
1		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	06/27/2007	

Labeler - CVS Pharmacy (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(59779-543) , pack(59779-543)

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(59779-543)