

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

*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.*

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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 (1-800-222-1222) 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**

**Distributed by: CVS Pharmacy, Inc.**

One CVS Drive, Woonsocket, RI 02895

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50844 REV0918C54309

**Drug Facts (continued)**

**Inactive ingredients** corn starch, croscarmellose (59-867)

■ store at 25°C (77°F); excursions permitted between 15°-30°C

■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN

**Drug Facts (continued)**

■ sodium, croscarmellose, 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

**Drug Facts (continued)**

**Active ingredients (in each caplet)**

**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 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

**Allergenic:** Acetaminophen may cause severe skin reactions. Symptoms may include: ■ rash ■ blisters ■ skin redness ■ 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 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)**

**Directions**

■ do not take more than directed

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**Drug Facts (continued)**

**Ask a doctor before use if you have**

■ high blood pressure

■ glaucoma

■ heart disease

■ 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 (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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#343025-PE

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PLASST RECYCLE

50644 REV0018054309

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

**CVS Health**

**Caplets**

**MAXIMUM STRENGTH**

**Severe Allergy & Sinus Headache**

ACETAMINOPHEN, DIPHENHYDRAMINE HCl, PHENYLEPHRINE HCl

B-0231-543-09-H  
REV0918054309

**CVS Health**

**Caplets**

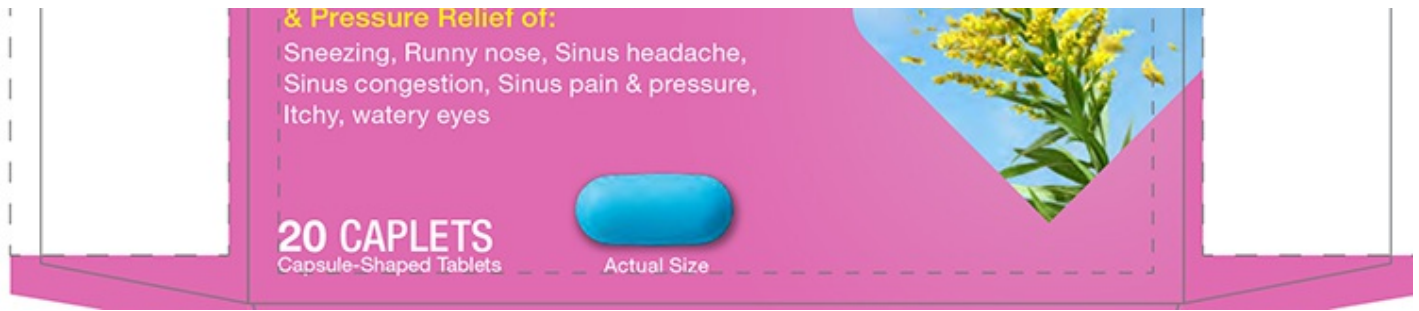
**MAXIMUM STRENGTH**

**Severe Allergy & Sinus Headache**

ACETAMINOPHEN, DIPHENHYDRAMINE HCl  
PHENYLEPHRINE HCl

Pain reliever, Antihistamine & Nasal decongestant

For Allergy Plus Sinus Pain



CVS Health 44-543

## SEVERE ALLERGY AND SINUS HEADACHE MAXIMUM STRENGTH

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-543
<b>Route of Administration</b>	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)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
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

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	16mm

<b>Flavor</b>		<b>Imprint Code</b>	44;543
<b>Contains</b>			
<b>Packaging</b>			
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b> <b>Marketing End Date</b>
1	NDC:59779-543-09	2 in 1 CARTON	06/27/2007
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product	
<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC MONOGRAPH FINAL	part341	06/27/2007	

**Labeler** - CVS Pharmacy (062312574)

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

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