

**SEVERE SINUS PAIN AND CONGESTION- acetaminophen, guaifenesin,  
phenylephrine hcl tablet, film coated  
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS 44-527**

***Active ingredients (in each caplet)***

Acetaminophen 325 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Expectorant  
Nasal decongestant

***Uses***

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
  - headache
  - nasal congestion
  - minor aches and pains
  - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

***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:

- blisters
- rash
- skin reddening

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.
- 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**

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- heart disease
- thyroid disease
- diabetes
- liver disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

### **Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin.

### **When using this product**

**do not exceed recommended dosage.**

### **Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough 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
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

### **If pregnant or breast-feeding,**

ask a health professional before use.

### **Keep out of reach of children.**

In case of 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
- swallow whole - do not crush, chew, or dissolve
- do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

### ***Other information***

- **each caplet contains:** sodium 3 mg
- **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)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

corn starch, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

### ***Principal Display Panel***

NDC 51316-927-08

**CVS™**

actual size

Non-Drowsy

### **SEVERE SINUS PAIN & CONGESTION**

#### **Acetaminophen**

Pain Reliever, Fever Reducer

Guaifenesin, Expectorant

Phenylephrine HCl, Nasal Decongestant

Compare to Tylenol®

Sinus Severe active ingredients\*

Relieves: Sinus headache, Sinus pressure, Chest congestion, Nasal congestion, Mucus

**24  
CAPLETS**

**Distributed by: CVS Pharmacy, Inc.**  
One CVS Drive, Woonsocket, RI 02895

\*This product is not manufactured or distributed by Kenvue Inc.,  
 owner of the registered trademark Tylenol® Sinus Severe.

50844 ORG092252708

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



actual size

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 & CONGESTION**

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 Pain Reliever, Fever Reducer  
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**Drug Facts (continued)**

**Uses**

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
  - headache
  - nasal congestion
  - minor aches and pains
  - sinus congestion and pressure

**Drug Facts (continued)**

- heart disease
- thyroid disease
- liver disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

**Asks a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

**When using this product do not exceed recommended dosage.**

**Stop use and ask a doctor if**

- you experience dizziness, or sleeplessness occur
- you have pain, nasal congestion, or cough gets worse or lasts more than 7 days
- you have fever, gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

**If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of 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
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- take 2 caplets every 4 hours
- swallow whole - do not crush, chew, or dissolve
- do not take more than 10 caplets in 24 hours
- children under 12 years: ask a doctor

**Drug Facts (continued)**

**Inactive ingredients** corn starch, croscopolone, flavor, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucrose, talc, titanium dioxide

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

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No Print/No Varnish  
 Lot & EXP

#970315

FPO 80%

UPC# 05042805397

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## SEVERE SINUS PAIN AND CONGESTION

acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:51316-927

<b>Route of Administration</b>	ORAL
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### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPROVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;527
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-927-08	2 in 1 CARTON	10/03/2025	
1		12 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	10/03/2025	

**Labeler** - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-927) , pack(51316-927)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-927)

### Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-927)

Revised: 11/2025

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED