

**SEVERE SINUS PAIN AND CONGESTION DAYTIME- acetaminophen,  
guaifenesin, phenylephrine hcl tablet, film coated  
CVS Pharmacy**

-----  
**CVS 44-527C-SC**

***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
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

***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**

- 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
- cough that occurs with too much phlegm (mucus)

### **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**

- redness or swelling is present
- 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
- 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***

**♥CVS**

Health®

Compare to the active ingredients in  
Tylenol® Sinus Severe\*

**Daytime**

**Non-Drowsy**

**Severe**

**Sinus Pain &  
Congestion**

**ACETAMINOPHEN**

Pain reliever, Fever reducer

**GUAIFENESIN**

Expectorant

**PHENYLEPHRINE HCl**

Nasal decongestant

Relieves:

Sinus headache,  
Sinus pressure, Chest  
congestion, Nasal

congestion & Mucus

**24** 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**

\*This product is not manufactured or  
distributed by Johnson & Johnson  
Corporation, owner of the registered  
trademark Tylenol® Sinus Severe.  
50844 REV0922D52708

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

One CVS Drive, Woonsocket, RI 02895

© 2023 CVS/pharmacy

CVS.com® 1-800-SHOP CVS

V-19849

✓ **CVS® Quality**

Money Back Guarantee



Compare to the active ingredients in Tylenol® Sinus Severe\*

Daytime

# Non-Drowsy Severe Sinus Pain & Congestion

**ACETAMINOPHEN**  
Pain reliever, Fever reducer

**GUAIFENESIN**

Expectorant

**PHENYLEPHRINE HCl**

Nasal decongestant

**Relieves:**

Sinus headache, Sinus pressure, Chest congestion, Nasal congestion & Mucus



Actual Size

24 CAPLETS

**Drug Facts**

**Active ingredients (in each caplet)**

- Acetaminophen 325 mg
- Guaifenesin 200 mg
- Phenylephrine HCl 5 mg

**Purpose**

Pain reliever/fever reducer  
Expectorant  
Nasal decongestant

**Drug Facts (continued)**

**Uses**

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

**Drug Facts (continued)**

- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

**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  
 ■ 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  
 ■ 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.  
 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.

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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- heart disease
- thyroid disease
- diabetes
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland
- cough that occurs with too much phlegm (mucus)
- liver disease
- if you have ever had an allergic reaction to this product or any of its ingredients

**Drug Facts (continued)**

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.

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

- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

**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 BUSTERS IS TORN OR BROKEN**  
 ■ store at 25° C (77° F); excursions permitted between 15°-30° C (59°-86° F)

**Drug Facts (continued)**

See end flap for expiration date and lot number

**Inactive ingredients** corn starch, croscollonite, flavor, magnesium stearate, methylcellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

**Drug Facts (continued)**

polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide  
 ■ **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTERS IS TORN OR BROKEN**  
 ■ store at 25° C (77° F); excursions permitted between 15°-30° C (59°-86° F)

**Questions or comments?**

1-800-426-9391

No Print/No Varnish  
 Lot and Expiration No.  
 TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BUSTERS UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING  
 This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® Sinus Severe.  
 50844  
 REV/092202708



Distributed by: CVS Pharmacy, Inc.  
 One CVS Drive, Woonsocket, RI 02895  
 © 2023 CVS/pharmacy  
 CVS.com® 1-800-SHOP CVS  
 V-19849



B-0231-527C-08SCHR  
 REV/092202708

CVS 44-527C

SEVERE SINUS PAIN AND CONGESTION DAYTIME			
acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:59779-275
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-275-08	2 in 1 CARTON	08/06/2005	
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	08/06/2005	

**Labeler** - CVS Pharmacy (062312574)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(59779-275) , pack(59779-275)

## Establishment

Name	Address	ID/FEI	Business Operations
------	---------	--------	---------------------

LNK International, Inc.		832867894	manufacture(59779-275)
-------------------------	--	-----------	------------------------

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(59779-275)

Revised: 1/2024

CVS Pharmacy