

**SINUS RELIEF SEVERE CONGESTION MAXIMUM STRENGTH- acetaminophen,  
guaifenesin, 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 44-615-SMH**

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

Acetaminophen 325 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever  
Expectorant  
Nasal decongestant

***Uses***

- temporarily relieves:
  - nasal congestion
  - headache
  - sinus congestion and pressure
  - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily promotes nasal and/or sinus drainage

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- with other drugs containing acetaminophen
- more than 4,000 mg in 24 hours, which is the maximum daily amount
- 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.
- 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**

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

- nervousness, dizziness, or sleeplessness occur
- fever gets worse or lasts more than 3 days
- pain, nasal congestion, or cough gets worse or lasts more than 7 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 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**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

**Other information**

- **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, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**Principal display panel**

♥ **CVS**  
**Health™**

Compare to the active ingredients in Maximum Strength Mucinex® SINUS-MAX® Severe Congestion Relief\*

**MAXIMUM STRENGTH**

**Sinus Relief**

**Severe Congestion**

**ACETAMINOPHEN** - Pain reliever

**GUAIFENESIN** - Expectorant

**PHENYLEPHRINE HCl** - Nasal decongestant

**Relieves:**

- Headache
- Nasal & Chest congestion

**Thins & Loosens mucus**

**20 CAPLETS** Ages 12 Years & Over

Actual Size

\*This product is not manufactured or distributed by Reckitt Benckiser LLC, owner of the registered trademark Maximum Strength Mucinex® SINUS-MAX® Severe Congestion Relief. 50844  
REV0117A61509

**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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**CVS® Quality**

Money Back Guarantee

#938777  
 0 50428 30714 4

No print/No varnish area  
 Lot no./Exp date

B-0231-615-09-SMH  
 REV0117A61509

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 Guaifenesin 200 mg  
 Phenylephrine HCl 5 mg  
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 Expectorant  
 Nasal decongestant

**Drug Facts (continued)**  
**Uses** ■ temporarily relieves: ■ nasal congestion ■ headache  
 ■ sinus congestion and pressure ■ minor aches and pains  
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the  
 bronchial passageways of bothersome mucus and make coughs more  
 productive ■ temporarily promotes nasal and/or sinus drainage

**Drug Facts (continued)**  
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 UNITS IS TORN, BROKEN OR SHOWS  
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Compare to the active ingredients  
 in Maximum Strength Mucinex®  
 SINUS-MAX® Severe Congestion Relief\*

**MAXIMUM STRENGTH**  
**Sinus Relief**  
**Severe Congestion**

**ACETAMINOPHEN** - Pain reliever  
**GUAIFENESIN** - Expectorant  
**PHENYLEPHRINE HCl** - Nasal decongestant

- Relieves:**
- Headache
  - Nasal & Chest congestion

Thins & loosens mucus

**20 CAPLETS** Ages 12 Years & Over Actual Size



CVS 44-615

**SINUS RELIEF SEVERE CONGESTION MAXIMUM STRENGTH**  
 acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:59779-515
<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
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 (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

### Product Characteristics

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19 mm
<b>Flavor</b>		<b>Imprint Code</b>	44;615
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59779-515-09	2 in 1 CARTON	06/30/2014	
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 FINAL	part341	06/30/2014	

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**Labeler - CVS Pharmacy (062312574)****Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		038154464	PACK(59779-515)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867894	MANUFACTURE(59779-515)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		967626305	PACK(59779-515)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		832867837	PACK(59779-515)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
LNK International, Inc.		868734088	PACK(59779-515)