

**MUCUS RELIEF SINUS PRESSURE PAIN AND COUGH- acetaminophen,  
dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated  
CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED**

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**CVS 44-617**

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

Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever  
Cough suppressant  
Expectorant  
Nasal decongestant

***Uses***

temporarily relieves:

- headache
- cough due to the common cold
- nasal congestion
- sinus congestion and pressure
- minor aches and pains
  
- temporarily promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and 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**

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

### **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**

- new symptoms occur
- 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
- 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**
- 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: do not use

### ***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, 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® Pressure, Pain & Cough\*

NDC 51316-627-09

#### **MAXIMUM STRENGTH**

**Mucus Relief**  
**Sinus Pressure,**  
**Pain & Cough**

**ACETAMINOPHEN** - Pain reliever  
**DEXTROMETHORPHAN HBr** - Cough suppressant  
**GUAIFENESIN** - Expectorant  
**PHENYLEPHRINE HCl** - Nasal decongestant

Relieves:

- Headache
- Sinus pressure & congestion
- Cough

Thins & loosens mucus  
Ages 12 Years & Over  
Actual Size

**20 CAPLETS**

**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 RB Health (US) LLC,  
owner of the  
registered trademark Maximum Strength Mucinex® Sinus-Max® Pressure,  
Pain & Cough.**

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50844  
ORG082361709**



Compare to the active ingredients in  
Maximum Strength Mucinex®  
Sinus-Max® Pressure, Pain & Cough\*

NDC 51316-627-09

# MAXIMUM STRENGTH Mucus Relief Sinus Pressure, Pain & Cough

**ACETAMINOPHEN** - Pain reliever  
**DEXTROMETHORPHAN HBr** - Cough suppressant  
**GUAIFENESIN** - Expectorant  
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DG8087A

### Drug Facts

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Acetaminophen 325 mg  
Dextromethorphan HBr 10 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

#### Purpose

Pain reliever  
Cough suppressant  
Expectorant  
Nasal decongestant

### KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

### Drug Facts (continued)

**Uses** ■ temporarily relieves:  
■ cough due to the common cold  
■ sinus congestion and pressure  
■ minor aches and pains  
■ temporarily promotes nasal and/or sinus drainage

### Drug Facts (continued)

■ helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and 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:  
■ hives ■ rash ■ 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.  
■ If you are now taking 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 ■ diabetes ■ thyroid disease ■ cough that occurs with too much phlegm (mucus) ■ difficulty in urination due to enlargement of the prostate gland ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ heart disease ■ high blood pressure

### Drug Facts (continued)

**Inactive ingredients** corn starch, croscarmellose, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, methylcellulose, polyethylene glycol, polyethylene glycol, polyvinyl alcohol, polyvinylpyrrolidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

### 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.

### Stop use and ask a doctor if

■ new symptoms occur  
■ 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  
■ 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.

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**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)  
■ see end flap for expiration date and lot number

### Drug Facts (continued)

**Questions or comments?** 1-800-426-9381

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**PARENTS:**  
Learn more about your medicine here  
www.StopMedicineAbuse.org

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

#938776

FP0 80%  
UPC# 050428088548  
XXXXXXXXXXXX

\*This product is not manufactured or distributed by RB Health (US) LLC, owner of the registered trademark Maximum Strength Mucinex® Sinus-Max® Pressure, Pain & Cough.

B-0231-617-09-SMH  
ORG082361709

No print/No varnish  
Lot & Exp date

CVS 44-617

## MUCUS RELIEF SINUS PRESSURE PAIN AND COUGH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51316-627
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 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		
<b>Inactive Ingredients</b>				
Ingredient Name		Strength		
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)				
<b>CROSPROVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)				
<b>FD&amp;C RED NO. 40 ALUMINUM LAKE</b> (UNII: 6T47AS764T)				
<b>FD&amp;C YELLOW NO. 6 ALUMINUM LAKE</b> (UNII: GYP6Z2JR6Q)				
<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>TALC</b> (UNII: 7SEV7J4R1U)				
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)				
<b>Product Characteristics</b>				
<b>Color</b>	red	<b>Score</b>	no score	
<b>Shape</b>	OVAL	<b>Size</b>	19mm	
<b>Flavor</b>		<b>Imprint Code</b>	44;617	
<b>Contains</b>				
<b>Packaging</b>				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-627-09	2 in 1 CARTON	04/03/2024	
1		10 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC Monograph Drug	M012	04/03/2024		

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

**Establishment**

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-627) , pack(51316-627)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-627)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-627)

Revised: 4/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED