

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

CVS 44-615 SM

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
 - minor aches and pains
 - sinus congestion and pressure
- 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:

- 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
- difficulty in urination due to enlargement of the prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- high blood pressure
- 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 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® Severe Congestion & Pain*

NDC 51316-516-09

MAXIMUM STRENGTH

Mucus Relief

Sinus Severe

Congestion & Pain

ACETAMINOPHEN - Pain reliever

GUAIFENESIN - Expectorant

PHENYLEPHRINE HCl - Nasal decongestant

Relieves:

- Sinus congestion
- Headache

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® Severe Congestion & Pain.

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50844
ORG062361509



Compare to the active ingredients in
Maximum Strength Mucinex®
Sinus-Max® Severe Congestion & Pain*

NDC 51316-516-09

MAXIMUM STRENGTH Mucus Relief Sinus Severe Congestion & Pain

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DG8087A

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B-0231-615-09-SMH
ORG062361509

No print/No varnish
Lot & Exp date

CVS 44-615

#938777
UPC# 050428088531
FP0 80%

TAMPER EVIDENT: DO NOT USE IF
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Drug Facts
Active Ingredients (in each caplet)
Acetaminophen 325 mg
Guaifenesin 200 mg
Phenylephrine HCl 5 mg

Drug Facts (continued)
Uses
temporarily relieves:
nasal congestion
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 passages of both the same mucus and make coughs more productive

Drug Facts (continued)
Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.

Warnings
User warnings: 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 redness
hives
rash
It is a skin reaction occurs, stop use and seek medical help right away.

Drug Facts (continued)
When using this product do not exceed recommended dosage.
Stop use and ask a doctor if:
nauseous, dizzy, or sleepiness 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.

Do not use
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difficulty in urination due to enlargement of the prostate gland
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Other Information
each caplet contains: sodium 3 mg
TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BUSTER IS TORN OR BROKEN
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see end flap for expiration date and lot number

Drug Facts (continued)
Inactive ingredients
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Drug Facts (continued)
Questions or comments? 1-800-428-9391
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06902361509

MUCUS RELIEF SINUS SEVERE CONGESTION AND PAIN			
acetaminophen, guaifenesin, phenylephrine hcl tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51316-516
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)	
FD&C RED NO. 40 ALUMINUM LAKE (UNII: 6T47AS764T)	
FD&C YELLOW NO. 6 ALUMINUM LAKE (UNII: GYP6Z2JR6Q)	
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	44;615
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51316-516-09	2 in 1 CARTON	04/03/2024	
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 Drug	M012	04/03/2024	

Labeler - CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	pack(51316-516)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(51316-516) , pack(51316-516)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(51316-516)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	pack(51316-516)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(51316-516)

Revised: 4/2024

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED