

**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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guaranteed.**
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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

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

- Relieves:**
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Actual Size

20 CAPLETS

DG8087A

#938777
 UPC# 050428088531
 FPO 80%

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

Drug Facts
Active Ingredients (in each caplet)
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 Guaifenesin 200 mg
 Pseudoephedrine HCl 5 mg

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 Pain reliever
 Expectorant
 Nasal decongestant

Drug Facts (continued)
Uses
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Drug Facts (continued)
 ■ 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.
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Drug Facts (continued)
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Drug Facts (continued)
Questions or comments? 1-800-428-9391

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B-0231-615-09-SMH
 ORG062361509

No print/No varnish
 Lot & Exp date

CVS 44-615

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: 4/2025

CVS WOONSOCKET PRESCRIPTION CENTER, INCORPORATED