

**SEVERE SINUS CONGESTION RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled**  
**Chain Drug Marketing Association Inc.**

*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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**Severe Sinus Congestion Relief**

**Active ingredients (in each softgel)**

**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:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
  - cough
- 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 12 liquid gels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily 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.

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

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to enlarged 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 use more than directed****Stop use and ask a doctor if**

- 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
- 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.**

**Overdose warning:**

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick 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 (see Overdose warning)**
- do not take more than 12 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours

- children under 12 years of age: do not use

**Other information**

- store between 20-25°C (68-77°F)
- avoid excessive heat

**Inactive ingredients**

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

**Questions or Comments?**

Call toll free: **248-449-9300**

**PRINCIPAL DISPLAY PANEL**

Severe Sinus Congestion Relief 16 SOFTGELS

NDC 63868-213-16

\*Compare to the active ingredients in Mucinex® Sinus-Max® Severe Congestion Relief



Maximum Strength  
**Severe  
Congestion Relief**

THIS PRODUCT IS PACKAGED IN  
A CHILD RESISTANT AND TAMPER  
EVIDENT PACKAGE. USE ONLY IF  
BLISTERS ARE INTACT.

NDC 63868-213-16



**\*\*Compare to the active  
ingredients in Mucinex®  
Sinus-Max® Severe  
Congestion Relief**

Maximum Strength  
**Severe  
Congestion Relief**

**Fast Relief**

Acetaminophen - Pain Reliever/Fever Reducer  
Dextromethorphan HBr - Cough Suppressant  
Guaifenesin - Expectorant  
Phenylephrine HCl - Nasal Decongestant

Relieves Sinus Congestion  
Thins & Loosens Mucus  
Relieves Headache  
Controls Cough



**16** Liquid Gels  
(Liquid Filled Capsules)

Non-Drowsy  
For Ages 12+

Maximum Strength  
**Severe  
Congestion Relief**



LOT NO:  
EXP DATE:

**COATING  
FREE AREA**



6 35515 99609 0



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

|   |  |   |
|---|--|---|
| <p><b>Drug Facts</b></p> <p><b>Active ingredients (in each softgel)</b></p> <p>Acetaminophen 325 mg.....Pain reliever<br/> Dextromethorphan HBr 10 mg.....Cough suppressant<br/> Guaifenesin 200 mg.....Expectorant<br/> Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p><b>Purposes</b></p> <ul style="list-style-type: none"> <li>temporarily relieves: <ul style="list-style-type: none"> <li>nasal congestion</li> <li>headache</li> <li>minor aches and pains</li> <li>sinus congestion and pressure</li> <li>cough</li> </ul> </li> <li>temporarily promotes nasal and/or sinus drainage</li> <li>helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive</li> </ul> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> <li>more than 12 softgels in 24 hours, which is the maximum daily amount</li> <li>with other drugs containing acetaminophen</li> <li>3 or more alcoholic drinks daily while using this product</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>skin reddening</li> <li>blisters</li> <li>rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Do not use</b></p> <ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>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.</li> </ul> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>liver disease</li> <li>heart disease</li> <li>diabetes</li> <li>high blood pressure</li> <li>thyroid disease</li> </ul> |  | <p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>trouble urinating due to an enlarged prostate gland</li> <li>persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> <li>cough that occurs with too much phlegm (mucus)</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</b></p> <p><b>When using this product do not use more than directed</b></p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>nervousness, dizziness, or sleeplessness occur</li> <li>pain, nasal congestion, or cough gets worse or lasts more than 7 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>redness or swelling is present</li> <li>new symptoms occur</li> <li>cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.</li> </ul> <p><b>If pregnant or breast-feeding, ask a health professional before use.</b></p> <p><b>Keep out of reach of children.</b></p> <p><b>Overdose warning</b> Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>do not take more than directed (see Overdose warning)</li> <li>do not take more than 12 softgels in any 24-hour period</li> <li>adults and children 12 years of age and older: take 2 softgels every 4 hours</li> <li>children under 12 years of age: do not use</li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>store between 15-30°C (59-86°F)</li> <li>avoid excessive heat</li> </ul> <p><b>Inactive ingredients</b></p> <p>FD&amp;C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink</p> <p><b>Questions or comments?</b></p> <p>Call toll free: 248-449-9300</p> <p><b>**This product is not manufactured or distributed by Reckitt Benckiser, owner of the registered trademarks Mucinex® Sinus-Max® Severe Congestion Relief.</b></p> |
|---|--|---|

\*Per 4-hour dose  
Do not take more than a total of 12 softgels in a 24-hour period  
Take only as directed.



**PARENTS:**  
Learn about teen medicine abuse  
www.StopMedicineAbuse.org

Distributed by C.D.M.A., Inc.®  
43157 W 9 Mile Rd  
Novi, MI 48375  
www.qualitychoice.com  
Questions: 248-449-9300



Made in China  
CDMA24-01



## SEVERE SINUS CONGESTION RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:63868-213 |
| Route of Administration | ORAL           |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength             | Strength |
|---|-------------------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)                    | ACETAMINOPHEN                 | 325 mg   |
| DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 10 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 |
|---|----------|
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8)                |          |
| GELATIN (UNII: 2G86QN327L)                          |          |
| GLYCERIN (UNII: PDC6A3C0OX)                         |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) |          |
| POVIDONE (UNII: FZ989GH94E)                         |          |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3)                 |          |
| SORBITOL (UNII: 506T60A25R)                         |          |
| SORBITAN (UNII: 6O92ICV9RU)                         |          |
| WATER (UNII: 059QF0K00R)                            |          |

## Product Characteristics

|          |                  |              |          |
|----------|------------------|--------------|----------|
| Color    | orange (Clear)   | Score        | no score |
| Shape    | capsule (Oblong) | Size         | 25mm     |
| Flavor   |                  | Imprint Code | PC26     |
| Contains |                  |              |          |

## Packaging

| # | Item Code        | Package Description                                    | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:63868-213-16 | 2 in 1 CARTON  | 07/13/2017           |                    |
| 1 |                  | 8 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                                  | 07/13/2017           |                    |

**Labeler** - Chain Drug Marketing Association Inc. (011920774)

## Establishment

| Name   | Address | ID/FEI    | Business Operations                          |
|--|---------|-----------|--|
| Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd |         | 421293287 | manufacture(63868-213) , analysis(63868-213) |

