

**SINUS RELIEF- acetaminophen, guaifenesin, phenylephrine hcl capsule, coated  
Kroger Company**

*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.*

-----

**Kroger Co. Sinus Relief Drug Facts**

**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
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an 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 persistent headache. 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 10 caplets in any 24-hour period
- adults and children 12 years and older: take 2 caplets every 4 hours
- children under 12 years of age: do not use

## **Other information**

- each caplet contains: sodium 4 mg
- store at 20-25°C (68-77°F)

## **Inactive ingredients**

croscarmellose sodium, crospovidone, FD&C yellow #6 aluminum lake, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

## **Questions or comments?**

1-800-632-6900

## **Package/Label Principal Display Panel**

COMPARE TO the active ingredients of MUCINEX® SINUS-MAX® SEVERE CONGESTION RELIEF CAPLETS

See side panel

SEE NEW WARNINGS

FOR AGES 12+

Sinus Relief

SEVERE CONGESTION RELIEF

Acetaminophen, Pain Reliever

Guaifenesin, Expectorant

Phenylephrine HCl, Nasal Decongestant

MAXIMUM STRENGTH

Clears Sinus Congestion

Relieves Headache

Thins & Loosens Mucus

20 CAPLETS

actual size

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202

QUALITY GUARANTEE  
www.kroger.com

GLUTEN FREE

\*\*Per 4-hour dose,  
dose every 4 hours  
Keep carton for complete  
product information



23 54 b2L6b :

**Drug Facts**

**Active ingredients (in each caplet)** Acetaminophen 325 mg... Pain reliever  
Guaifenesin 200 mg... Expectorant  
Phenylephrine HCl 5 mg... Nasal decongestant

**Purpose**

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

**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 redness ■ 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 ■ heart disease ■ diabetes ■ high blood pressure ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland

**Drug Facts (continued)**

■ 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 than directed

When using this product do not use more than directed

Stop use and ask a doctor if: ■ nervousness, dizziness, or sleepiness 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 persistent headache. 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: In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). 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 10 caplets in any 24-hour period ■ adults and children 12 years and older: take 2 caplets every 4 hours ■ children under 12 years of age: do not use

**Other information**

■ each caplet contains: sodium 4 mg ■ store at 20-25°C (68-77°F)

**Inactive ingredients** croscarmellose sodium, croscopolone, FD&C yellow #5 aluminum lake, malvidexin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

**Questions or comments?** 1-800-632-9900

\*MUCINEX® SINUS-MAX® ARE REGISTERED TRADEMARKS OF RECKITT BENCKISER LLC. PARISIPANY, NJ 07054. RECKITT BENCKISER LLC IS NOT AFFILIATED WITH THE KROGER CO. OR THIS PRODUCT.  
Do not use if blister unit is broken or torn



# Sinus Relief

SEVERE CONGESTION RELIEF

MAXIMUM STRENGTH\*\*

Acetaminophen, Pain Reliever  
Guaifenesin, Expectorant  
Phenylephrine HCl, Nasal Decongestant

COMPARE TO the active ingredients of MUCINEX® SINUS-MAX®  
SEVERE CONGESTION RELIEF CAPLETS \*See side panel

SEE NEW WARNINGS

NDC 30142-997-01



# Sinus Relief

SEVERE CONGESTION RELIEF

Acetaminophen, Pain Reliever  
Guaifenesin, Expectorant  
Phenylephrine HCl, Nasal Decongestant

MAXIMUM STRENGTH\*\*

- Clears Sinus Congestion
- Relieves Headache
- Thins & Loosens Mucus



actual size

20  
CAPLETS

## SINUS RELIEF

acetaminophen, guaifenesin, phenylephrine hcl capsule, coated

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:30 142-997
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
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**

<b>Ingredient Name</b>	<b>Strength</b>
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
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)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

**Product Characteristics**

<b>Color</b>	ORANGE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	L145
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-997-01	10 in 1 CARTON	04/08/2015	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph final	part341	04/08/2015	

