

**SINUS RELIEF- acetaminophen, guaifenesin, diphenhydramine hcl, phenylephrine hcl
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 Day Time Night Time Drug Facts

Active ingredients (in each caplet) – SINUS RELIEF Day

Acetaminophen 325 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Active ingredients (in each caplet) – SINUS RELIEF Night

Acetaminophen 325 mg

Diphenhydramine HCl 25 mg

Phenylephrine HCl 5 mg

Purpose – SINUS RELIEF Day

Pain reliever

Expectorant

Nasal decongestant

Purpose – SINUS RELIEF Night

Pain reliever

Antihistamine

Nasal decongestant

Uses

- temporarily relieves:
- nasal congestion
- headache
- minor aches and pains
- sinus congestion and pressure
- runny nose and sneezing (SINUS RELIEF Night only)
- 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 (SINUS RELIEF Day only)

Warnings

Liver warning: These products contain 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 these products

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.
- with any other product containing diphenhydramine, even one used on skin (SINUS RELIEF Night only)
- 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 these products.
- if you have ever had an allergic reaction to these products or any of their 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
- glaucoma (SINUS RELIEF Night only)
- a breathing problem such as emphysema or chronic bronchitis (SINUS RELIEF Night only)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (SINUS RELIEF Day only)
- cough that occurs with too much phlegm (mucus) (SINUS RELIEF Day only)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (SINUS RELIEF Night only)

When using these products

- do not use more than directed

- excitability may occur, especially in children (SINUS RELIEF Night only)
- marked drowsiness may occur (SINUS RELIEF Night only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (SINUS RELIEF Night only)
- avoid alcoholic drinks (SINUS RELIEF Night only)
- be careful when driving a motor vehicle or operating machinery (SINUS RELIEF Night only)

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, cough or nasal congestion 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. (SINUS RELIEF Day only)

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 (SINUS RELIEF Day only)
- store at 20-25°C (68-77°F)

Inactive ingredients (SINUS RELIEF Day only)

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

Inactive ingredients (SINUS RELIEF Night only)

crospovidone, FD&C blue #1 aluminum lake, magnesium stearate, 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 – SINUS RELIEF Day

COMPARE TO the active ingredients of MUCINEX® SINUS-MAX®

See side panel

FOR AGES 12+

MAXIMUM STRENGTH

Sinus Relief

Acetaminophen, Pain Reliever

Guaifenesin, Expectorant

Phenylephrine HCl, Nasal Decongestant

Day Time

Relieves Sinus Pressure, Headache & Congestion

Thins & Loosens Mucus

actual size

10 CAPLETS

SEE NEW WARNINGS

Package/Label Principal Display Panel – SINUS RELIEF Night

COMPARE TO the active ingredients of MUCINEX® SINUS-MAX®

See side panel

FOR AGES 12+

MAXIMUM STRENGTH

Sinus Relief

Acetaminophen, Pain Reliever

Diphenhydramine HCl, Antihistamine

Phenylephrine HCl, Nasal Decongestant

Night Time

Relieves Nasal Congestion, Sinus Pressure & Pain

Relieves Runny Nose & Sneezing

10 CAPLETS

actual size

SEE NEW WARNINGS

COMPARE TO the active ingredients of MUCINEX® SINUS-MAX®

*See side panel

FOR AGES 12+

NDC 30142-688-80



MAXIMUM STRENGTH**

Sinus Relief


DayTime

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

- Relieves Sinus Pressure, Headache & Congestion
- Thins & Loosens Mucus



actual size

10
CAPLETS

SEE NEW WARNINGS


Night Time

Acetaminophen, Pain Reliever
Diphenhydramine HCl,
Antihistamine
Phenylephrine HCl,
Nasal Decongestant

- Relieves Nasal Congestion, Sinus Pressure & Pain
- Relieves Runny Nose & Sneezing



actual size

10
CAPLETS



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

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202
QUALITY GUARANTEE
www.kroger.com

GLUTEN FREE

Drug Facts

Active ingredients (in each caplet)
SINUS RELIEF Day

Acetaminophen 325 mg.....Pain reliever
Guaifenesin 200 mg.....Expectorant
Phenylephrine HCl 5 mg.....Nasal decongestant

Active ingredients (in each caplet)
SINUS RELIEF Night

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Uses

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- headache ■ minor aches and pains
- sinus congestion and pressure
- runny nose and sneezing
(*SINUS RELIEF Night only*)
- 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 (*SINUS RELIEF Day only*)

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- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using these products

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:
■ skin reddening ■ blisters ■ rash
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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.
■ with any other product containing diphenhydramine, even one used on skin (*SINUS RELIEF Night only*) ■ 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. ▶

Drug Facts (continued)

If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking these products. ■ if you have ever had an allergic reaction to these products or any of their 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 ■ glaucoma (*SINUS RELIEF Night only*)
- a breathing problem such as emphysema or chronic bronchitis (*SINUS RELIEF Night only*)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (*SINUS RELIEF Day only*)
- cough that occurs with too much phlegm (mucus) (*SINUS RELIEF Day only*)

Ask a doctor or pharmacist before use if you are ■ taking the blood thinning drug warfarin
■ taking sedatives or tranquilizers (*SINUS RELIEF Night only*)

When using these products

- do not use more than directed
- excitability may occur, especially in children (*SINUS RELIEF Night only*) ■ marked drowsiness may occur (*SINUS RELIEF Night only*)
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- avoid alcoholic drinks (*SINUS RELIEF Night only*)
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Drug Facts (continued)

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 of age 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 (*SINUS RELIEF Day only*) ■ store at 20-25°C (68-77°F)

Inactive ingredients (SINUS RELIEF Day only)

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

Inactive ingredients (SINUS RELIEF Night only)

crospovidone, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments?

1-800-632-6900

Do not take the day and night caplets at the same time.
Do not take more than a total of 10 caplets in a 24-hour period.
Take only as directed.

*Mucinex® Sinus-Max® are registered trademarks of Reckitt Benckiser LLC, Parsippany, NJ 07054. Reckitt Benckiser LLC is not affiliated with The Kroger Co. or these products.

Do not use if blister unit is broken or torn

SINUS RELIEF

acetaminophen, guaifenesin, diphenhydramine hcl, phenylephrine hcl kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-688
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-688-80	1 in 1 KIT; Type 0: Not a Combination Product	04/10/2015	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	5 BLISTER PACK	10
Part 2	5 BLISTER PACK	10

Part 1 of 2

SINUS RELIEF

acetaminophen, guaifenesin, phenylephrine hcl tablet, coated

Product Information

Route of Administration	ORAL
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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
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

Color	ORANGE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	L145
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 CARTON		
1		2 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	04/08/2015	

Part 2 of 2

SINUS RELIEF

acetaminophen, diphenhydramine hcl, phenylephrine hcl tablet, coated

Product Information

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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

Color	BLUE	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	L625
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		5 in 1 CARTON		
1		2 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		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/10/2015	

Labeler - Kroger Company (006999528)

Revised: 11/2020

Kroger Company