SINUS RELIEF- acetaminophen, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride
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) SINUS RELIEF Day

Acetaminophen 325 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever

Expectorant

Nasal decongestant

Active ingredients (in each caplet) SINUS RELIEF Night

Acetaminophen 325 mg

Diphenhydramine HCl 12.5 mg

Phenylephrine HCl 5 mg

Purposes

Pain reliever

Antihistamine/cough suppressant

Nasal decongestant

Uses

- temporarily relieves:
- nasal congestion
- headache
- minor aches and pains
- sinus congestion and pressure
- runny nose and sneezing **(NIGHT only)**
- cough **(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 **(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 **(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 **(NIGHT only)**
- a breathing problem such as emphysema or chronic bronchitis **(NIGHT only)**
- 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
- taking sedatives or tranquilizers **(NIGHT only)**

When using these products

- **do not use more than directed**
- excitability may occur, especially in children **(NIGHT only)**
- marked drowsiness may occur **(NIGHT only)**

- alcohol, sedatives, and tranquilizers may increase drowsiness **(NIGHT only)**
- avoid alcoholic drinks **(NIGHT only)**
- be careful when driving a motor vehicle or operating machinery **(NIGHT only)**

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: 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 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 **(DAY only)**
- store at 20-25°C (68-77°F)

Inactive ingredients (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 (NIGHT only)

crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 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

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

See side panel

FOR AGES 12+

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

Night Time

Acetaminophen, Pain Reliever

Diphenhydramine HCl, Antihistamine

Cough Suppressant

Phenylephrine HCl, Nasal Decongestant

Relieves Nasal Congestion, Sinus Pressure & Pain

Relieves Runny Nose, Sneezing & Cough

10 CAPLETS

actual size

**Per 4-hour dose, dose every 4 hours

Do not use if blister unit is broken or torn

GLUTEN FREE

Take only as directed
Keep carton for complete product information.

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

0 41260 00837 5

COMPARE TO the active ingredients of MUCINEX® SINUS-MAX®
*See side panel

FOR AGES 12+

NDC 30142-415-90

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

Night Time

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

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

10 CAPLETS

actual size

Do not take DAY and NIGHT caplets at the same time. Do not take more than a total of 10 caplets in a 24-hour period.
Do not take the first dose of the NIGHT caplets sooner than 4 hours after the last dose of the DAY caplets unless directed by a doctor.

*Mucinex® Sinus-Max® are registered trademarks of RB Health (US) LLC,
Parsippany, NJ 07054. RB Health (US) LLC is not affiliated with
The Kroger Co. or these products.

Drug Facts

Active ingredients (in each caplet) SINUS RELIEF Day	Purposes
Acetaminophen 325 mg	Pain reliever
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Active ingredients (in each caplet) SINUS RELIEF Night	Purposes
Acetaminophen 325 mg	Pain reliever
Diphenhydramine HCl 12.5 mg	Antihistamine/ cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves: ■ nasal congestion ■ headache ■ minor aches and pains ■ sinus congestion and pressure ■ runny nose and sneezing *(NIGHT only)* ■ cough *(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 *(DAY only)*

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

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■ 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 *(NIGHT only)*

▶

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 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 *(NIGHT only)* ■ a breathing problem such as emphysema or chronic bronchitis *(NIGHT only)* ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema ■ cough that occurs with too much phlegm (mucus)

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When using these products

■ **do not use more than directed** ■ excitability may occur, especially in children *(NIGHT only)* ■ marked drowsiness may occur *(NIGHT only)* ■ alcohol, sedatives, and tranquilizers may increase drowsiness *(NIGHT only)* ■ avoid alcoholic drinks *(NIGHT only)* ■ be careful when driving a motor vehicle or operating machinery *(NIGHT only)*

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■ 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.

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Drug Facts (continued)

Directions

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Other information

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Inactive ingredients (DAY only)

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Inactive ingredients (NIGHT only)

crospovidone, FD&C blue #1 aluminum lake, FD&C blue #2 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

SINUS RELIEF

acetaminophen, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-415

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:30142-415-90	1 in 1 KIT; Type 0: Not a Combination Product	11/25/2019	

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 hydrochloride tablet, film 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
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)	
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
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		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		

Part 2 of 2

SINUS RELIEF

acetaminophen, diphenhydramine hydrochloride, phenylephrine hydrochloride, tablet, film 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	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPOVIDONE (15 MPA.S AT 5%) (UNII: 68401960MK)	

FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
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**	L27H
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	11/25/2019	

Labeler - Kroger Company (006999528)

Revised: 12/2019 Kroger Company