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



The Kroger Co. or these products Parsippany, NJ 07054. R8 Health (US) LLC is not affiliated with *Mucinex*5 inus -Max* are registered trademarks of RB Health (US) LLC.

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

Do not take DAY and NIGHT caplets at the same time. Do not take more than

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Drug Facts	Drug Facts (continued)
Active ingredients Purposes (in each caplet) SINUS RELIEF Day Acetaminophen 325 mgPain reliever Guaifenesin 200 mgPain reliever Guaifenesin 200 mgNasal decongestant Phenylephrine HCI 5 mgNasal decongestant Active ingredients Purposes (in each caplet) Purposes	 if you are now taking a prescription monoxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional condor Parkinson's disease), or for 2 weeks affistopping the MAOI drug, if you do not know your prescription drug contains an MAOI, a doctor or pharmacist before taking these priming if you have ever had an allergic reaction these products or any of their ingredients
SINUS RELIEF Night Acetaminophen 325 mgPain reliever Diphenhydramine HCI Antihistamine/ 12.5 mgCough suppressant Phenylephrine HCI 5 mgNasal decongestant	Ask a doctor before use if you have ■ liver disease ■ heart disease ■ dia ■ high blood pressure ■ thyroid diseas ■ trouble urinating due to an enlarged pro- gland ■ glaucoma (NIGHT only) ■ a breathing problem such as emphysen
Uses temporarily relieves: Inasal congestion headache Iminor aches and pains sinus congestion and pressure runny nose and sneezing (NIGHT only) cough (NIGHT only)	chronic bronchitis (NIGHT only) persistent or chronic cough such as occ with smoking, asthma, chronic bronchitis, emphysema cough that occurs with the much phlegm (mucus)
temporarily promotes nasal and/or sinus drainage	Ask a doctor or pharmacist before use are ■ taking the blood thinning drug w ■ taking sedatives or tranquilizers (NIGH)
 helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (DAY only) 	When using these products do not use more than directed excitability may occur, especially in chil (NIGHT only) marked drowsiness marked
Warnings Liver warning: These products contain acetaminophen. Severe liver damage may occur if you take ■ more than 4,000 mg of acetaminophen in	occur (NIGHT only) alcohol, sedative tranquilizers may increase drowsiness (Ni only) avoid alcoholic drinks (NIGHT be careful when driving a motor vehicle operating machinery (NIGHT only)
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.	Stop use and ask a doctor if nervous ness, dizziness, or slee pless ness pain, nasal congestion or cough gets we lasts more than 7 days fever gets we lasts more than 3 days redness or sw is present new symptoms occur cough comes back or occurs with rash headache that lasts. These could be signs serious condition.
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 pregnant or breast-feeding, ask a heap professional before use. Keep out of reach of children. Overdose warning: In case of overdose, get medical or contact a Poison Control Center right aw (1-800-222-1222). Quick medical attentio critical for adults as well as for children ew you do not notice any signs or symptoms.

Drug Facts (continued) if you are now taking a prescription monoamine xidase inhibitor (MAOI) (certain drugs for epression, psychiatric, or emotional conditions, r Parkinson's disease), or for 2 weeks after topping the MAOI drug. If you do not know if our prescription drug contains an MAOI, ask a octor or pharmacist before taking these products. if you have ever had an allergic reaction to ese products or any of their ingredients sk a doctor before use if you have liver disease ■ heart disease ■ diabetes high blood pressure thyroid disease trouble urinating due to an enlarged prostate and glaucoma (NIGHT only) a breathing problem such as emphysema or hronic bronchitis (NIGHT only) persistent or chronic cough such as occurs in smoking, asthma, chronic bronchitis, or mphysema cough that occurs with too nuch phlegm (mucus) sk a doctor or pharmacist before use if you re taking the blood thinning drug warfarin taking sedatives or tranquilizers (NIGHT only) hen using these products do not use more than directed excitability may occur, especially in children NIGHT only) marked drowsiness may ccur (NIGHT only) alcohol, sedatives, and anguilizers may increase drowsiness (NIGHT n/v) avoid alcoholic drinks (NIGHT on lv) be careful when driving a motor vehicle or perating machinery (NIGHT only) top use and ask a doctor if I nervous ness, dizziness, or sleepless ness occur pain, nasal congestion or cough gets worse or asts more than 7 days 🔳 fever gets worse or asts more than 3 days 🛛 redness or swelling s present 🛛 🔳 new symptoms occur cough comes back or occurs with rash or eadache that lasts. These could be signs of a erious condition. pregnant or breast-feeding, ask a health rofessional before use. eep out of reach of children. Overdose varning: In case of overdose, get medical help r contact a Poison Control Center right away -800-222-1222). Quick medical attention is itical for adults as well as for children even if

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 (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

SINUS RELIEF

acetaminophen, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride kit

Product Information	ion						
Product Type	HUMAN OTC DRUG	Item Code (Source)		I	NDC:30142-415		
Packaging							
# Item Code	Package Descriptio			ing Start Date Marketi		ng End Date	
1 NDC:30142-415-90	1 in 1 KIT; Type 0: Not a Combinatio	; Type 0: Not a Combination Product 11/25/2019					
Quantity of Parts							
-				tal Product Qu	antity		
Part 1 5 BLISTER PAC		10		-	0		
Part 2 5 BLISTER PAC	K	10					
Part 1 of 2							
SINUS RELIEF	7						
acetaminophen, gua	fanasin nhanylanhrina hydrochl						
	irenesiii, phenyiephrine nyurochi	oride tablet,	film coated	đ			
	itenesiii, phenyiephrine nyurochi	oride tablet,	film coated	1			
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Product Informati		oride tablet,	film coated	1			
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	ion	oride tablet,	film coated	1			
Route of Administrat	ion ORAL	oride tablet,	film coated	1			
	ion ORAL	oride tablet,	film coated		Strength	Strength	
Route of Administrat Active Ingredient	ion ORAL				•	Strength 325 mg	
Route of Administrat Active Ingredient	ion ion ORAL /Active Moiety Ingredient Name	- UNII:362091		Basis of S	•	_	
Route of Administrat Active Ingredient ACETAMINOPHEN (UN GUAIFENESIN (UNII: 49	ion ion ORAL /Active Moiety Ingredient Name NII: 36209ITL9D) (ACETAMINOPHEN	- UNII:362091 95W7451VQ)	TL9D)	Basis of S ACETAMINOPH	E	325 mg	
Route of Administrat Active Ingredient ACETAMINOPHEN (UN GUAIFENESIN (UNII: 49 PHENYLEPHRINE HYD	ion ion ORAL /Active Moiety Ingredient Name NII: 36209ITL9D) (ACETAMINOPHEN 95W7451VQ) (GUAIFENES IN - UNII:49	- UNII:362091 95W7451VQ)	TL9D)	Basis of S ACETAMINOPH GUAIFENES IN PHENYLEPHRIN	E	325 mg 200 mg	
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I OLI VIIVIL ALCOHOL,	UNSPECIFIED (UNII: 5	I: 3WJQ0SDW1A) 32B59J990)				
POVIDONE, UNSPECIFIE	D (UNII: FZ989GH94E)					
SILICON DIO XIDE (UNII:	ETJ7Z6XBU4)					
STEARIC ACID (UNII: 4EL)	V7Z65AP)					
TALC (UNII: 7SEV7J4R1U)						
TITANIUM DIO XIDE (UNI	I: 15FIX9V2JP)					
Product Characteris	tics					
Color	ORANGE	Score		no score		
Shape	OVAL	Size				
Flavor		Imprint Code			L145	
Contains		.				
Dealerster						
Packaging	D 1 D			NG 1	- E. I.D.	
# Item Code	Package Des	•	arketing Start Date	Marketin	g End Date	
1 2 in 1 BLI	STER PACK; Type 0: No	ot a Combination Product				
Marketing Inform						
Marketing Category	Application Number	an Managyanh Citatian	Jarkating Start Date	Marketin	g End Date	
	art341	r or Monograph Citation M	Marketing Start Date			
OTC monograph final p		r or monograph Citation	Markeung Start Date		5 Line Dan	
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FD&C BLUE NO. 1 (UNI	II: H3R47	K3TBD)					
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)							
MAGNESIUM STEARAT	E (UNII:	70097M6I30)					
MICROCRYSTALLINE	CELLUI	LOSE (UNII: OP1R32D	6 1U)				
POLYETHYLENE GLYC	COL, UN	SPECIFIED (UNII: 3W	JQ0SDW1A)				
POLYVINYL ALCOHO	L, UNSP	ECIFIED (UNII: 532B5	9J990)				
POVIDONE, UNSPECIF	IED (UN	II: FZ989GH94E)					
SILICON DIO XIDE (UN	II: ETJ7Z	6XBU4)					
STEARIC ACID (UNII: 41	ELV7Z65	SAP)					
TALC (UNII: 7SEV7J4R1	U)						
TITANIUM DIO XIDE (U	NII: 15FD	X9 V2JP)					
Product Character	istics						
Color		BLUE	Score		no score		
Shape		OVAL	Size		16 mm		
Flavor			Imprint Code		L27H		
Contains							
Packaging							
# Item Code		Package Descrip	tion	Marketing Start Dat	e Marke	ting End Date	
1 2 in 1 B	LISTER	PACK; Type 0: Not a C	Combination Product				
Marketing Information							
Marketing Category			Monograph Citation	Marketing Start Dat	te Marka	ting End Date	
OTC monograph final	part341		donograph Chadon	Marke ung Start Dat		ting Life Date	
o re monograph mar	puito41						
Marketing Information							
Marketing Category			Monograph Citation	Marketing Start Dat	te Marke	ting End Date	
OTC monograph final	part341			11/25/2019		ang Liiu Date	
O 1 C monographi final	pa11341			11/23/2013			

Labeler - Kroger Company (006999528)

Revised: 12/2019

Kroger Company