MUCUS RELIEF SINUS DAY AND NIGHT- acetaminophen, diphenhydramine hydrochloride, guaifenesin, and phenylephrine hydrochloride
HEB

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.

HEB - 1169 - 2019-1004

Drug Facts

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

Active ingredients (in each Sinus Night caplet)	***Purpose***
Acetaminophen 325 mg	Pain reliever
Diphenhydramine HCl 25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves:
  - nasal congestion
  - headache
  - minor aches and pains
  - sinus congestion and pressure
  - runny nose and sneezing (SINUS NIGHT ONLY)
- 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 DAY ONLY)

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 12 caplets 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.
- with any other product containing diphenhydramine, even one used on skin (SINUS 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 this product.

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 NIGHT ONLY)
- a breathing problem such as emphysema or chronic bronchitis (SINUS NIGHT ONLY)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (SINUS DAY ONLY)
- cough that occurs with too much phlegm (mucus) (SINUS DAY ONLY)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (SINUS NIGHT ONLY)

When using this product

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

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 (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 Sinus Day and Sinus Night caplets at the same time
- do not take more than 12 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

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

SINUS DAY

colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

SINUS NIGHT

colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Compare to Mucinex® Sinus-Max™ Day & Night active ingredients†
NDC 37808-269-01

H-E-B

Maximum Strength*

Sinus Relief

Daytime

Acetaminophen /Pain Reliever

Dextromethorphan HBr / Cough Suppressant

Guaifenesin / Expectorant

Phenylephrine / Nasal Decongestant

Relief of:

• Sinus Pressure

• Headache • Congestion

• Thins & Loosens Mucus

10 Day Caplets

Nighttime

Acetaminophen /Pain Reliever

Diphenhydramibne HCl / Cough Suppressant

Phenylephrine / Nasal Decongestant

Relief of:

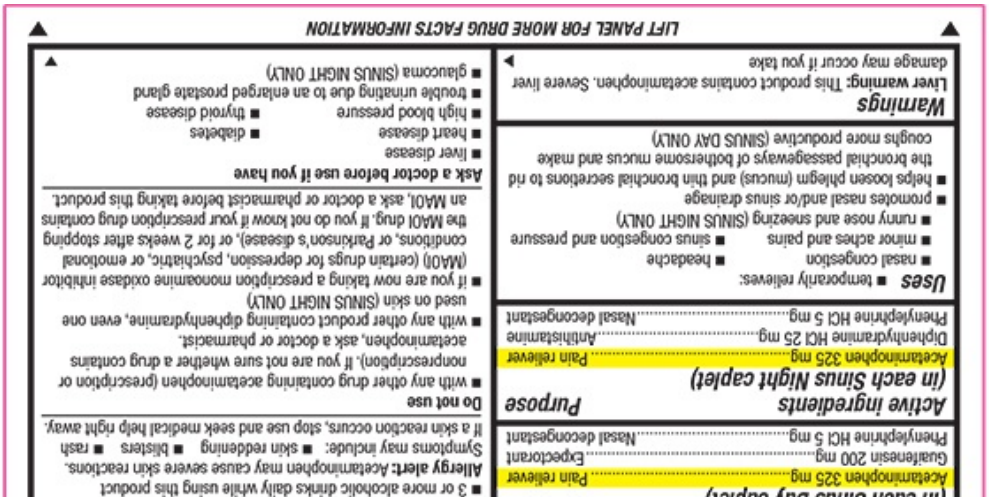
• Nasal Congestion

• Sinus Pressure & Pain

• Runny Nose • Sneezing

10 Night Caplets

For Ages 12+



H-E-B

Maximum Strength*

Sinus Relief

Daytime & Nighttime

Compare to *Mucinex® Sinus-Max™ Day & Night* active ingredients†

NDC 37808-269-01

H-E-B

Maximum Strength*

Sinus Relief

Daytime

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

Relief of:
- Sinus Pressure
- Headache • Congestion
- Thins & Loosens Mucus

10 DAY CAPLETS

Nighttime

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

Relief of:
- Nasal Congestion
- Sinus Pressure & Pain
- Runny Nose • Sneezing

10 NIGHT CAPLETS

NC

NC

H-E-B

Maximum Strength*

Sinus Relief

Daytime & Nighttime

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

†This product is not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Sinus-Max™ Day & Night.

*Per 4-hour dose, dose every 4 hours

Questions or Comments? 1-844-705-4384

100% GUARANTEE If you aren't completely pleased with this product, we'll be happy to refund your purchase price. You have our word on it.

DISTRIBUTED BY H-E-B®
SAN ANTONIO, TX 78204

Drug Facts

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

Drug Facts (continued)

- more than 12 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

DO NOT TAKE DAY AND NIGHT CAPLETS TOGETHER
DO NOT TAKE MORE THAN A TOTAL OF 12 CAPLETS IN A 24-HOUR PERIOD

Drug Facts (continued)

- a breathing problem such as emphysema or chronic bronchitis (SINUS NIGHT ONLY)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema (SINUS DAY ONLY)
- cough that occurs with too much phlegm (mucus) (SINUS DAY ONLY)

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers (SINUS NIGHT ONLY)

When using this product
- **do not use more than directed**
- excitability may occur, especially in children (SINUS NIGHT ONLY)
- marked drowsiness may occur (SINUS NIGHT ONLY)
- alcohol, sedatives, and tranquilizers may increase drowsiness (SINUS NIGHT ONLY)
- avoid alcoholic drinks (SINUS NIGHT ONLY)
- be careful when driving a motor vehicle or operating machinery (SINUS 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 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.

Drug Facts (continued)

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 (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

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- **do not take Sinus Day and Sinus Night caplets at the same time**
- do not take more than 12 caplets in any 24-hour period
- adults and children 12 years and older: take 2 caplets every 4 hours
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Other information

- store between 20-25°C (68-77°F) in a dry place
- retain carton for complete product information

Inactive ingredients

SINUS DAY colloidal silicon dioxide, croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide

SINUS NIGHT colloidal silicon dioxide, copovidone, croscarmellose sodium, FD&C blue #1, hypromellose, lactose anhydrous, magnesium stearate, povidone, pregelatinized starch, propylene glycol, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

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MUCUS RELIEF SINUS DAY AND NIGHT

acetaminophen, diphenhydramine hydrochloride, guaifenesin, and phenylephrine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:37808-269

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:37808-269-01	1 in 1 CARTON	04/01/2015	08/31/2023

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BLISTER PACK	10
Part 2	1 BLISTER PACK	10

Part 1 of 2

ACETAMINOPHEN, GUAIFENESIN, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, guaifenesin, and phenylephrine hydrochloride 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
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**
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	orange	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	AAA;1166
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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

ACETAMINOPHEN, DIPHENHYDRAMINE HYROCHLORIDE, PHENYLEPHRINE HYDROCHLORIDE

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride 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	

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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
COPOVIDONE (UNII: D9C330MD8B)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL (capsule-shaped)	**Size**	17mm
Flavor		**Imprint Code**	AAA;1116
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		10 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	04/01/2015	08/31/2023

Labeler - HEB (007924756)

Revised: 11/2021 HEB