CAREONE SINUS RELIEF DAY TIME SINUS RELIEF NIGHT TIME- acetaminophen, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride
American Sales 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.

American Sales Company Sinus Relief Day Time Sinus Relief Night Time 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?

1-800-719-9260

Package/Label Principal Display Panel

COMBINATION PACK

Compare to the active ingredients in Mucinex® Sinus-Max® Day

SINUS RELIEF DAY TIME

Pain Reliever – Acetaminophen

Expectorant – Guaifenesin

Nasal Decongestant – Phenylephrine HCl

Maximum Strength

Relieves Sinus Pressure, Headache & Congestion

Thins & Loosens Mucus

Actual Size

For Ages 12+

Gluten Free

OUR PHARMACISTS RECOMMEND

10 CAPLETS

Compare to the active ingredients in Mucinex® Sinus-Max® Night

SINUS RELIEF NIGHT TIME

Pain Reliever – Acetaminophen

Antihistamine/Cough Suppressant – Diphenhydramine HCl

Nasal Decongestant – Phenylephrine HCl

Maximum Strength

Relieves Nasal Congestion, Sinus Pressure & Pain

Relieves Runny Nose, Sneezing & Cough

Actual Size

For Ages 12+

Gluten Free

OUR PHARMACISTS RECOMMEND

10 CAPLETS

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

Do not use if blister unit is broken or torn

*These products are not manufactured or distributed by Reckitt Benckiser, distributor of Mucinex® Sinus-Max®.

DISTRIBUTED BY FOODHOLD U.S.A., LLC
LANDOVER, MD 20785 · 1-877-846-9949

Quality guaranteed or your money back.

3 41520 00423 0

COMBINATION PACK

CAREone®

*Compare to the active ingredients in Mucinex® Sinus-Max® Day**

SINUS RELIEF DAY TIME

Pain Reliever - **Acetaminophen**
Expectorant - Guaifenesin
Nasal Decongestant - Phenylephrine HCl

Maximum Strength**
Relieves Sinus Pressure, Headache & Congestion
Thins & Loosens Mucus

Actual Size

For Ages 12+
Gluten Free

10 CAPLETS

CAREone®

NDC 41520-806-80

*Compare to the active ingredients in Mucinex® Sinus-Max® Night**

SINUS RELIEF NIGHT TIME

Pain Reliever - **Acetaminophen**
Antihistamine/Cough Suppressant - Diphenhydramine HCl
Nasal Decongestant - Phenylephrine HCl

Maximum Strength**
Relieves Nasal Congestion, Sinus Pressure & Pain
Relieves Runny Nose, Sneezing & Cough

Actual Size

For Ages 12+
Gluten Free

10 CAPLETS

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.
Take only as directed
Keep carton for complete product information.

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)*

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)*

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)

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. ▶

Drug Facts (continued)

Directions

- **do not take more than directed (see Overdose warning)**
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Other information

- **each caplet contains:** sodium 4 mg *(DAY only)*
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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?

1-800-719-9260

04M80 OF C1

CAREONE SINUS RELIEF DAY TIME SINUS RELIEF NIGHT TIME

acetaminophen, guaifenesin, phenylephrine hydrochloride, diphenhydramine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41520-806

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:41520-806-80	1 in 1 KIT; Type 0: Not a Combination Product	10/08/2019	

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

CAREONE SINUS RELIEF DAY TIME

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

CAREONE SINUS RELIEF NIGHT TIME

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	10/08/2019	

Labeler - American Sales Company (809183973)

Revised: 12/2019 American Sales Company