

SINUS RELIEF SEVERE CONGESTION AND PAIN- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
CARDINAL HEALTH

LEA-1167-2021-0127

Drug Facts

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

Uses

- temporarily relieves:
 - nasal congestion
 - headache
 - minor aches and pains
 - sinus congestion and pressure
- 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

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.
- 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
- 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

When using this product do not use more than directed

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 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 outer package for complete product information

Inactive ingredients

colloidal silicon dioxide, corn starch, 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

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

LEADER™

NDC 70000-0080-1

Maximum Strength

Sinus Relief

Severe Congestion & Pain

Acetaminophen | Guaifenesin | Phenylephrine HCl

Pain Reliever | Expectorant | Nasal Decongestant

Clears Sinus Congestion

Relieves Headache

Thins & Loosens Mucus

For Ages 12+

20 CAPLETS

Actual Size

COMPARE TO MUCINEX® SINUS-MAX® MAXIMUM STRENGTH SEVERE CONGESTION & PAIN active ingredients†

100% Money Back Guarantee

**Maximum Strength
Sinus Relief
Severe Congestion & Pain**



<p>Drug Facts</p> <p>Active ingredients (in each caplet)</p> <p>Acetaminophen 325 mg Pain reliever Guaifenesin 200 mg Expectorant Phenylephrine HCl 5 mg Nasal decongestant</p>	<p>Purpose</p> <p>Pain reliever</p>	<p>Uses</p> <ul style="list-style-type: none"> temporarily relieves: <ul style="list-style-type: none"> headache nasal congestion minor aches and pains sinus congestion and pressure 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 	<p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take</p> <ul style="list-style-type: none"> 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 <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> skin redness blisters rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p>	<p>Do not use</p> <ul style="list-style-type: none"> with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. 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. <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> diabetes heart disease liver disease high blood pressure thyroid disease trouble urinating due to an enlarged prostate gland cough that occurs with too much phlegm (mucus) 	<p>Other information</p> <ul style="list-style-type: none"> store between 20-25°C (68-77°F) in a dry place retain outer package for complete product information and warnings <p>Inactive ingredients</p> <p>colloidal silicon dioxide, corn starch, croscarmellose sodium, croscopolone, FDAC red #40 aluminum lake, FDAC yellow #6 aluminum lake, magnesium stearate, methylcellulose, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, stearic acid, talc, titanium dioxide</p>
<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema <p>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</p> <p>When using this product do not use more than directed</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> nauseousness, 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 <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p>		<p>Directions</p> <ul style="list-style-type: none"> do not take more than directed (see Overdose warning) 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 	<p>Questions or comments?</p> <p>1-844-705-4384</p> <p>DISTRIBUTED BY CARDINAL HEALTH, DUBLIN, OHIO 43017 WWW.MYLEADER.COM 1-800-200-6313 © 2021 CARDINAL HEALTH, LEADER, and LOGOs are trademarks of Cardinal Health.</p> <p>All other marks are the property of their respective owners.</p>	<p>100% Money Back Guarantee</p> <p>Return to place of purchase if not satisfied.</p> <p>DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN</p> <p>Maximum Strength per 4-Hour Dose</p> <p>This product is not manufactured or distributed by Recell Brackets, distributor of Mucnex® Sinus-Max® Maximum Strength Severe Congestion & Pain.</p>	

**Maximum Strength
Sinus Relief
Severe Congestion & Pain**



NDC 70000-0080-1

**Maximum Strength
Sinus Relief
Severe Congestion & Pain**

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

Clears Sinus Congestion
Relieves Headache
Thins & Loosens Mucus
For Ages 12+



Actual Size

20 CAPLETS

**COMPARE TO MUCINEX®
SINUS-MAX® MAXIMUM
STRENGTH SEVERE
CONGESTION & PAIN
active ingredients!**

100% Money Back Guarantee

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SINUS RELIEF SEVERE CONGESTION AND PAIN

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0080
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (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: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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	NDC:70000-0080-1	2 in 1 CARTON	01/27/2021	

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 Drug	M012	01/27/2021	

Labeler - CARDINAL HEALTH (063997360)

Revised: 11/2023

CARDINAL HEALTH