

SEVERE CONGESTION- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Harmon Stores Inc.

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.

HAR - 1167 - 2019-1009

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
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, 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

PRINCIPAL DISPLAY PANEL

CORE VALUES

Compare to the active ingredients in Mucinex® Sinus-Max Congestion Relief

MAXIMUM STRENGTH

Mucus / Sinus Relief

Severe Congestion

Acetaminophen, Guaifenesin, Phenylephrine HCl

Pain Reliever, Expectorant, Nasal Decongestant

For relief of:

Sinus Congestion & Headache

Thins & Loosens Mucus

Actual Size

20 CAPLETS

FOR AGES 12+

MAXIMUM STRENGTH[†]
Mucus/Sinus Relief
 Severe Congestion

<p>Drug Facts</p> <p>Active ingredients (in each caplet) Acetaminophen 325 mg.....Pain reliever Guaifenesin 200 mg.....Expectorant Phenylephrine HCl 5 mg.....Nasal decongestant</p> <p>Uses ■ temporarily relieves: ■ 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> <p>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.</p> <p>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.</p> <p>Ask a doctor before use if you have ■ diabetes ■ liver disease ■ high blood pressure ■ trouble urinating due to an enlarged prostate gland ■ cough that occurs with too much phlegm (mucus) ▶</p>	<p>Drug Facts (continued)</p> <p>■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema 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</p> <p>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.</p> <p>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</p> <p>Other information ■ store between 20-25°C (68-77°F) in a dry place ■ retain outer package for complete product information</p> <p>Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, croscopolone, 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</p>
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DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

†Per 4-hour dose, dose every 4 hours
 This product is not manufactured or distributed by Hechtel Benckiser, distributor of Mucinex[®] Sinus-Max[™] Severe Congestion Relief.

SATISFACTION GUARANTEED
 Or Your Money Back
 Visit us at: www.facevalues.com
 Liberty Procurement Co. Inc.
 650 Liberty Ave.
 Union, NJ 07083 USA



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MAXIMUM STRENGTH[†]
Mucus/Sinus Relief
 Severe Congestion

CORE VALUES™

Compare to active ingredients in Mucinex[®] Sinus-Max[™] Severe Congestion Relief*

MAXIMUM STRENGTH[†]
Mucus/Sinus Relief
 Severe Congestion

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

- For relief of:
- Sinus Congestion & Headache
 - Thins & Loosens Mucus

20 CAPLETS FOR AGES 12+



Actual Size

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-337
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)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LM26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
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	NDC:63940-337-02	2 in 1 CARTON	09/11/2018	
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	09/11/2018	

Labeler - Harmon Stores Inc. (804085293)

Revised: 10/2019

Harmon Stores Inc.