## SINUS SEVERE- 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.

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#### HAR - 1119 - 2019-1009

#### **Drug Facts**

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever
Acetanimophen 323 mg	reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

#### Uses

- temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:
  - sinus congestion and pressure
  - headache
  - nasal congestion
  - minor aches and pains
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

#### Warnings

#### Liver warning

This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3,250 mg acetaminophen) in 24 hours. 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 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.

• if you have ever had an allergic reaction to this product or any of its ingredients

#### Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 exceed recommended dosage

#### 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)

adults and children 12 years and over	<ul> <li>take 2 caplets every 4 hours</li> <li>swallow whole – do not crush, chew, or dissolve</li> <li>do not take more than 10 caplets in 24 hours</li> </ul>
children under 12 years	■ ask a doctor

#### Other information

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

#### **Inactive ingredients**

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

#### PRINCIPAL DISPLAY PANEL

**CORE VALUES** 

Compare to the active ingredients in Tylenol® Sinus Severe

Sinus Severe

for Adults

Acetaminophen, Phenylephrine HCl, Guaifenesin

Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant

Actual Size

For relief of:

Sinus Headache, Nasa Congestion

Sinus Pressure, Mucus + Chest Congestion

**DAYTIME NON-DROWSY** 

24 CAPLETS

"Cool Taste"

sificon dioxide, croscarmellose sodium, crospovidone, flavor, acesulfame potassium, colloidal inactive ingredients

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

Drug Facts (continued)

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nund racts (continued)

notice any signs or symptoms.

keep out of reach of children.

■ redness or swelling is present

Stop use and ask a doctor if

Drug Facts (continued)

thinning drug warfarin

These could be signs of a serious condition.

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■ nervousness, dizziness, or sleeplessness occur

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years and over

children 12

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■ winor acnes and pains

"This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol®

Distributed by Liberty Procurement Co. In 650 Liberty Ave. Union, NJ 07083 USA

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN

SATISFACTION GUARANTEED Or Your Money Back Visit us at: www.facevalues.com

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**Drug Facts** (continued)



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Active ingredients (in each caplet) Purpose

Drug Facts

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**Drug Facts** (continued)

## **CORE** VALUES\*\*

Compare to active ingredients in Tylenol® Sinus Severe\*

# Sinus Severe for Adults

Acetaminophen, Phenylephrine HCI, Guaifenesin Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant

Nasal Congestion

Actual Size



For relief of:

- Sinus Headache
- Sinus Pressure
- Mucus + Chest Congestion

24 CAPLETS

"Cool Taste"

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63940-330
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg	
<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	

Inactive Ingredients	
Ingredient Name	Strength
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPO VIDO NE, UNSPECIFIED (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
PO VIDO NE, UNS PECIFIED (UNII: FZ989 GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	

Product Characteristics			
Color	white	Score	no score
Shape	OVAL	Size	19 mm
Flavor	MINT	Imprint Code	AAA;1119
Contains			

Packaging					
#	Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
1	NDC:63940-330-02	2 in 1 CARTON	09/11/2018		
1		12 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.