

**SINUS SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**DISCOUNT DRUG MART**

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**1119-DDM-2021-1130**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purpose</b>
Acetaminophen 325 mg	Pain reliever/fever 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)**

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adults and	<ul style="list-style-type: none"><li>▪ take 2 caplets every 4 hours</li><li>▪ swallow whole - do not</li></ul>
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children 12 years and over	crush, chew, or dissolve ▪ do not take more than 10 caplets in 24 hours
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**

DISCOUNT drug mart FOOD FAIR

†Compare to the active ingredients in Tylenol® Sinus Severe

DAY, NON-DROWSY

FOR ADULTS

SINUS SEVERE

Acetaminophen, Phenylephrine HCl, Guaifenesin

Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant

RELIEF OF:

- SINUS HEADACHE
- SINUS PRESSURE
- NASAL CONGESTION
- MUCUS + CHEST CONGESTION

24 COOL TASTE CAPLETS

Actual Size



F111905DDM\_R1

**Drug Facts (continued)**  
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 ■ retain carton for complete product information  
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**Drug Facts (continued)**  
 ■ do not take more than directed (see overdose warning)  
 adults and children 12 years and over  
 ■ take 2 caplets every 4 hours  
 ■ swallow whole – do not crush, chew, or dissolve  
 ■ do not take more than 10 caplets in 24 hours  
 children under 12 years  
 ■ ask a doctor

**Drug Facts (continued)**  
**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 redness ■ 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.  
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**Ask a doctor before use if you have**  
 ■ liver disease ■ heart disease ■ high blood pressure  
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 ■ trouble urinating due to an enlarged prostate gland  
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**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.  
**Keep out of reach of children.**  
 If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition.  
 ■ cough comes back or occurs with rash or headache that lasts  
 ■ fever or swelling is present  
 ■ new symptoms occur  
 ■ fever gets worse or lasts more than 3 days  
 ■ pain, nasal congestion, or cough gets worse or lasts more than 7 days  
 ■ nervousness, dizziness, or sleeplessness occur  
**Stop use and ask a doctor if**  
 When using this product do not exceed recommended dosage  
**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin**  
**Drug Facts (continued)**  
 ■ cough that occurs with too much phlegm (mucus)  
 ■ Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

**Drug Facts**  
**Active ingredients (in each caplet) Purpose**  
 Acetaminophen 325 mg.....Pain reliever/fever reducer  
 Guaifenesin 200 mg.....Expectorant  
 Phenylephrine HCl 5 mg.....Nasal decongestant  
**Uses**  
 ■ temporarily relieves these symptoms associated with

**Drug Facts (continued)**  
 have fever or other upper respiratory allergies, and the common cold:  
 ■ sinus congestion and pressure ■ headache  
 ■ minor aches and pains  
 ■ nasal congestion  
 ■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive  
 ■ temporarily reduces fever

**DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN**

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Tylenol® Sinus Severe.

Distributed by: Drug Mart - Food Fair  
 211 Commerce Drive • Medina, OH 44256  
 SATISFACTION GUARANTEED  
 IF DISSATISFIED, RETURN UNUSED PORTION AND PACKAGING TO STORE WHERE PURCHASED. IF UNABLE TO RETURN TO STORE, SEND REASON FOR DISSATISFACTION, NAME, ADDRESS AND EMPLOYER TO: DISSATISFACT DRUG MART, 2111 COMMERCIAL DRIVE, MEDINA, OHIO 44229

†Compare to the active ingredients in Tylenol® Sinus Severe

**DAY, NON-DROWSY FOR ADULTS**

# SINUS SEVERE

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

- RELIEF OF:**
- SINUS HEADACHE
  - SINUS PRESSURE
  - NASAL CONGESTION
  - MUCUS + CHEST CONGESTION

**24 COOL TASTE CAPLETS**



NC

NC

NC

# SINUS SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53943-319
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>ACESULFAME POTASSIUM</b> (UNII: 23OV73Q5G9)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MINT	<b>Imprint Code</b>	AAA;1119
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53943-319-05	2 in 1 CARTON	11/13/2009	
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 Drug	M012	11/13/2009	

**Labeler** - DISCOUNT DRUG MART (047741335)

Revised: 10/2024

DISCOUNT DRUG MART