

**SEVERE SINUS RELIEF- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated**  
**AMERIFOODS TRADING COMPANY**

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**1119-FIR-2023-1102**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>Purpose</i></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 and warnings

### **Inactive ingredients**

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

### **Questions or comments?**

1-844-705-4384

### **PRINCIPAL DISPLAY PANEL**

First Street®

NDC 61504-119-05

†COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® SINUS SEVERE  
DAYTIME • NON-DROWSY

SEVERE

Sinus relief

Acetaminophen, Phenylephrine HCl, Guaifenesin

Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

For Relief of:

Sinus Headache

Sinus Pressure

Nasal Congestion

Mucus + Chest Congestion

ACTUAL SIZE

FOR ADULTS

# 24 COOL TASTE CAPLETS



## SEVERE SINUS RELIEF

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:61504-119
<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>CROSCARMELOSE 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</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:61504-119-05	2 in 1 CARTON	10/30/2023	
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	10/30/2023	

**Labeler** - AMERIFOODS TRADING COMPANY (626388680)

Revised: 11/2023

AMERIFOODS TRADING COMPANY