

# **SINUS CONGESTION AND PAIN SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated TopCare**

*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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**1119 - TCR - 2018-1228**

## **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)**

adults and children 12 years and over	<ul style="list-style-type: none"> <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	<ul style="list-style-type: none"> <li>▪ ask a doctor</li> </ul>

**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**

TopCare® Health

NDC 36800-505-05

Compare to Tylenol® Sinus Severe Active Ingredients†

Non-Drowsy Daytime

Sinus Severe

Severe

Our Pharmacists Recommend

Acetaminophen, Phenylephrine HCl, Guaifenesin

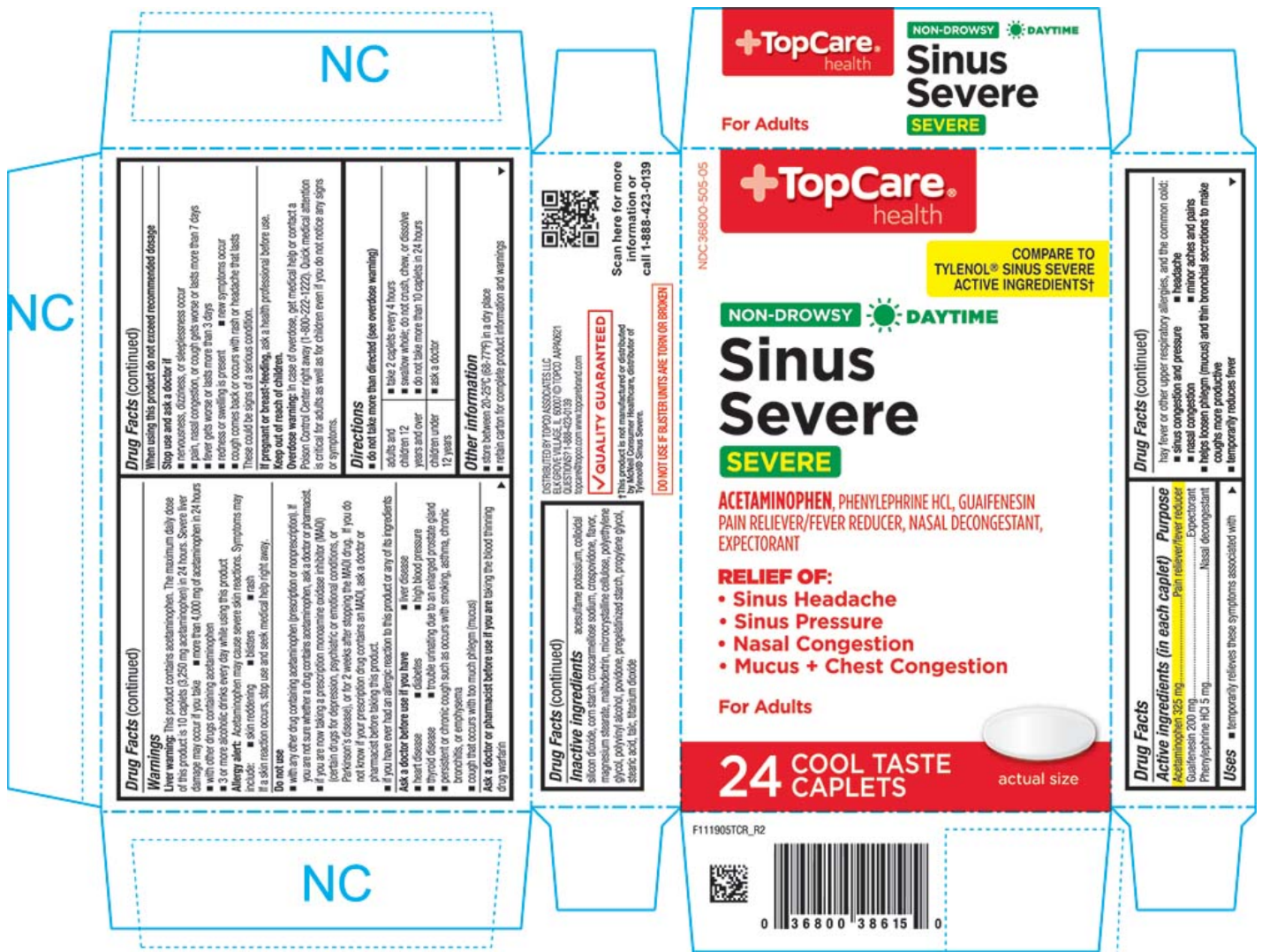
Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

Relief Of

- Sinus Headache • Sinus Pressure
- Nasal Congestion • Mucus + Chest Congestion

24 COOL TASTE CAPLETS

For Adults



## SINUS CONGESTION AND PAIN SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:36800-505
<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: 230V73Q5G9)	

<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</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:36800-505-05	2 in 1 CARTON	07/01/2013	
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	07/01/2013	

**Labeler** - TopCare (006935977)