

**SEVERE SINUS CONGESTION AND PAIN- acetaminophen, guaifenesin,  
phenylephrine tablet, coated  
Shield Pharmaceuticals Corp**

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**Severe Sinus Congestion and Pain**

***Drug Facts***

***Active ingredients (in each caplet)***

Acetaminophen 325 mg  
Guaifenesin 200 mg  
Phenylephrine HCl 5 mg

***Purpose***

Pain reliever/fever reducer  
Expectorant  
Nasal decongestant

***□ Uses***

- temporarily relieves these symptoms associated with hay fever or other 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 dose

### **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 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	ask a doctor

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## Other information

- store between 20-25° C (68-77° F)

## Questions or comments?

**1-800-373-6981** (toll-free)

## Inactive ingredients

croscarmellose sodium, colloidal silicon dioxide, dibasic calcium phosphate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, purified water, starch, talc, titanium dioxide

Distributed by:

**Shield Pharmaceuticals Corp.**  
Ronkonkoma, NY 11779

## PRINCIPAL DISPLAY PANEL

Compare to the active ingredients in Tylenol® Sinus Severe

Severe Sinus Congestion & Pain

Acetaminophen,  
Guaifenesin, Phenylephrine HCl

Carton



SEVERE SINUS CONGESTION AND PAIN			
acetaminophen, guaifenesin, phenylephrine tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83059-0107
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	5 mg
Inactive Ingredients			
Ingredient Name			Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)			
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)			
HYPROMELLOSES (UNII: 3NXW29V3WO)			
MAGNESIUM STEARATE (UNII: 70097M6I30)			
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)			
POVIDONE (UNII: FZ989GH94E)			
WATER (UNII: 059QF0KO0R)			
STARCH, CORN (UNII: O8232NY3SJ)			
TALC (UNII: 7SEV7J4R1U)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
CROSPVIDONE (UNII: 2S7830E561)			
MALTODEXTRIN (UNII: 7CVR7L4A2D)			
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)			
STEARIC ACID (UNII: 4ELV7Z65AP)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	SD32;44;527
Contains			
Packaging			
		Marketing Start	Marketing End

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83059-0107-1	1 in 1 CARTON	11/08/2025	
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	11/08/2025	

**Labeler** - Shield Pharmaceuticals Corp (118724924)

Revised: 11/2025

Shield Pharmaceuticals Corp