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

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)

	 take 2 caplets every 4 hours
adults and children 12 years and over	• 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

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.

Hauppauge, NY 11788

PRINCIPAL DISPLAY PANEL

Compare to the active ingredients in Tylenol® Sinus Severe Severe Sinus Congestion & Pain

Acetaminophen, Guaifenesin, Phenylephrine HCl

Carton



Drug Facts (continued)

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'This product is not manufactured or distributed by Johnson & Johnson er Inc. Mc Neil Consumer Healthcale, owner of the registered trademark Tyle nol™ Sinus Severe

Made in India ORG. 08/24

ValuRx



Severe Sinus Congestion & Pain

Acetaminophen,

Guaifenesin, Phenylephrine HCl,

Pain Reliever/Fever Reducer, Expectorant, Nasal Decongestant

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

12 caplets

Actual Size

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

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SEVERE SINUS CONGESTION AND PAIN

acetaminophen, quaifenesin, phenylephrine tablet, coated

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:83059-0029

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)	ACETAMINOPHEN	325 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)

PHENYLEPHRINE

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE 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)		

5 mg

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE	Size	20mm
Flavor		Imprint Code	SD8
Contains			

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:83059- 0029-1	1 in 1 CARTON	04/08/2024		
1		12 in 1 BOTTLE; 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	04/08/2024	

Labeler - Shield Pharmaceuticals Corp (118724924)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)