

TYLENOL SINUS SEVERE- acetaminophen, guaifenesin, phenylephrine hydrochloride tablet, coated
Jones Healthcare Group - Packaging Services, Inc

Tylenol Sinus Severe

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:

If a skin reaction occurs, stop use and seek medical help right away.

- skin reddening
- blisters
- rash

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**

adults and children 12 years and over	<ul style="list-style-type: none">• 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

Other information

- sodium 3 mg **each caplet contains:**
- store between 20-25°C (68-77°F)
- **do not use if carton is opened or if blister unit is broken**

Inactive ingredients

carnauba wax, croscarmellose sodium, flavor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sucralose, titanium dioxide, triacetin

Questions or comments?

call (toll-free) or (collect) **1-877-895-3665215-273-8755**

Package Labeling:



TYLENOL SINUS SEVERE

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67414-507
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 HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3Z D4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

TRIACETIN (UNII: XHX3C3X673)

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	20mm
Flavor	MINT	Imprint Code	TYLENOL;1072
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67414-507-04	50 in 1 CARTON	01/25/2018	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67414-507-00	2500 in 1 BOX	01/25/2018	
2		2 in 1 POUCH; 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	01/25/2018	

Labeler - Jones Healthcare Group - Packaging Services, Inc (243261024)

Registrant - Jones Healthcare Group - Packaging Services, Inc (243261024)

Establishment

Name	Address	ID/FEI	Business Operations
Janssen Cilag SpA		542797928	manufacture(67414-507)

Revised: 11/2023

Jones Healthcare Group - Packaging Services, Inc