

SINUS SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
CHAIN DRUG CONSORTIUM

1119-PRV-2020-0823

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
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	<ul style="list-style-type: none">▪ take 2 caplets every 4 hours▪ swallow whole - do not
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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

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

Questions or comments?

1-844-705-4384

PRINCIPAL DISPLAY PANEL

Premier Value®

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® SINUS SEVERE
FOR ADULTS

Sinus Severe

DAYTIME • NON-DROWSY

Acetaminophen, Phenylephrine HCl, Guaifenesin

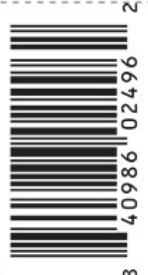
Pain Reliever / Fever Reducer, Nasal Decongestant, Expectorant

Relieves:

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

24 COOL TASTE CAPLETS

ACTUAL SIZE



F111905PRV_R1



Drug Facts (continued)
Other information
 ■ store between 20-25°C (68-77°F) in a dry place
 ■ retain carton for complete product information
Inactive ingredients
 acetylsalicylic acid, croscarmellose sodium, crospovidone, talc, silicon dioxide, croscarmellose sodium, crospovidone, talc, croscarmellose sodium, crospovidone, talc, silicon dioxide, croscarmellose sodium, crospovidone, talc, silicon dioxide
Questions or comments?
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Drug Facts (continued)
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. ■ 3 or more alcoholic drinks every day while using this product
Do not use
 ■ with any other drug containing acetaminophen (prescription or non-prescription). 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 the product or any of its ingredients
Ask a doctor before use if you have
 ■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
Directions
 ■ do not take more than directed (see overdose warning)
 adults and children 12 years and over ■ take 2 caplets every 4 hours ■ do not take more than 10 caplets in 24 hours ■ ask a doctor
 children under 12 years
Drug Facts (continued)
Warnings
 ■ 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
 ■ 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
 ■ cough comes back or occurs with rash or headache that lasts
 These could be signs of a serious condition.
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
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Drug Facts (continued)
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Drug Facts (continued)

DO NOT USE IF BLISTER UNITS ARE TORN OR BROKEN



This product is not manufactured or distributed by McKel Consumer Healthcare, distributor of Tylenol® Sinus Severe.
 Distributed By:
 Pharmacy Value Alliance, LLC
 407 East Lancaster Avenue
 Wayne, PA 19087
 If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

COMPARE TO THE ACTIVE INGREDIENTS IN
TYLENOL® SINUS SEVERE†

FOR ADULTS

Sinus Severe

DAYTIME • NON-DROWSY

Acetaminophen, Phenylephrine HCl, Guaifenesin
 Pain Reliever/Fever Reducer, Nasal Decongestant, Expectorant

Relieves:

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

24 COOL TASTE CAPLETS

NC

NC

NC

SINUS SEVERE

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-504
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
ACESULFAME POTASSIUM (UNII: 23OV73Q5G9)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor	MINT	Imprint Code	AAA;1119
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-504-24	2 in 1 CARTON	11/01/2009	07/31/2026
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	11/01/2009	07/31/2026

Labeler - CHAIN DRUG CONSORTIUM (101668460)

Revised: 10/2024

CHAIN DRUG CONSORTIUM