

SINUS CONGESTION AND PAIN SEVERE- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated
Strategic Sourcing Services LLC

SMK - 1119 - 2018-1230

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

PRINCIPAL DISPLAY PANEL

sunmark®

compare to Tylenol® Sinus Severe active ingredients†

NDC 49348-117-04

sinus severe

for adults

Non-Drowsy

Daytime

Sinus headache, sinus pressure, nasal congestion, mucus + chest congestion

Pain Reliever/Fever Reducer ACETAMINOPHEN

Nasal Decongestant PHENYLEPHRINE HCL

Expectorant GUAIFENESIN

COOL TASTE INSTANT COOLING SENSATION

24 CAPLETS



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

acesulfame potassium, colloidal silicon dioxide, croscarmellose sodium, crospovidone, flavor, magnesium stearate, malleodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylene glycol, stearic acid, talc, titanium dioxide

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.

- with other drugs containing acetaminophen
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- if you have ever had an allergic reaction to this product or any of its ingredients

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Ask a doctor before use if you have

- high blood pressure
- heart disease
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- 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
- swallow whole – do not crush, chew, or dissolve

children under 12 years

- ask a doctor

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.

Keep out of reach of children.

If pregnant or breast-feeding, ask a health professional before use. These could be signs of a serious condition:

- cough comes back or occurs with rash or headache that lasts
- redness or swelling is present
- fever gets worse or lasts more than 3 days
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
- nervousness, dizziness, or sleeplessness occur
- skin rash, hives, or other allergic reactions occur

Stop use and ask a doctor if

- when using this product do not exceed recommended dosage

Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin

Drug Facts (continued)

Uses

- temporarily relieves these symptoms associated with

Active Ingredients (in each caplet) Purpose

- Acetaminophen 325 mg: Pain reliever/fever reducer
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- Phenylephrine HCl 5 mg: Nasal decongestant

†This product is not manufactured or distributed by McKell Consumer Healthcare, distributor of Tylenol® Sinus Severe

MEKESON

Another Quality Product
Distributed by Mekesson
One Post Street, San Francisco, CA 94104
Money Back Guarantee
Please visit us at www.sunmarkbrand.com

DO NOT USE IF RUSTIER UNITS ARE JOIN OR BROKEN

Drug Facts (continued)

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- minor aches and pains
- nasal congestion
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- temporarily reduces fever

NC

sinus severe

for adults

Non-Drowsy Daytime

Sinus headache, sinus pressure, nasal congestion, mucus + chest congestion

Pain Reliever / Fever Reducer **ACETAMINOPHEN**
Nasal Decongestant **PHENYLEPHRINE HCl**
Expectorant **GUAIFENESIN**

COOL TASTE INSTANT COOLING SENSATION

24 CAPLETS

NC

COMPARE TO TYLENOL® SINUS SEVERE ACTIVE INGREDIENTS†
NDC 49348-117-04

SINUS CONGESTION AND PAIN SEVERE
acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-117
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)	
CROSCARMELOSE 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 (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:49348-117-04	2 in 1 CARTON	10/27/2014	06/30/2025
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date
OTC Monograph Drug	M012	10/27/2014	06/30/2025

Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 10/2023

Strategic Sourcing Services LLC