

TYLENOL SINUS SEVERE- acetaminophen tablet, coated
R J General Corporation

TYLENOL[®] SINUS SEVERE

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 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)**

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

- **each caplet contains:** sodium 3 mg
- store between 20-25°C (68-77°F)
- **do not use if pouch is torn or damaged**

Inactive ingredients

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

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

Made in Italy

Distributed by:

JOHNSON & JOHNSON
CONSUMER INC.

McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA

Repackaged and distributed by:

RJ General
2024 Northwest Drive
Cincinnati OH 45231

PRINCIPAL DISPLAY PANEL

TYLENOL[®]
FOR ADULTS
SINUS SEVERE

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

- SINUS HEADACHE
- SINUS PRESSURE
- NASAL CONGESTION
- MUCUS + CHEST CONGESTION

DAY
NON-DROWSY

50 Pouches of 2 Caplets each

TYLENOL[®]

FOR ADULTS

SINUS SEVERE

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



- SINUS HEADACHE
- SINUS PRESSURE
- NASAL CONGESTION
- MUCUS + CHEST CONGESTION



TYLENOL[®]

FOR ADULTS

SINUS SEVERE

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



50 Pouches of 2 Caplets each

How can we help?
 1-877-895-3665



Drug Facts

Active Ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Guafenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
 - nasal 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: The 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

Drug Facts (continued)

- 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
- The se 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. (1-800-232-1122) 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	take 2 caplets every 4 hours
	swallow whole; do not crush, chew or disolve
	do not take more than 10 caplets in 24 hours
children under 12 years	ask a doctor

Other information

- each caplet contains: sodium 3 mg
- store between 20-25°C (68-77°F)
- do not use if pouch is torn or damaged

Inactive ingredients: camellubawax, croscarmellose sodium, flacor, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, sucralose, titanium dioxide, triacetin

Questions or comments?

call 1-877-895-3665 (toll-free) or 215-273-8755 (collect)

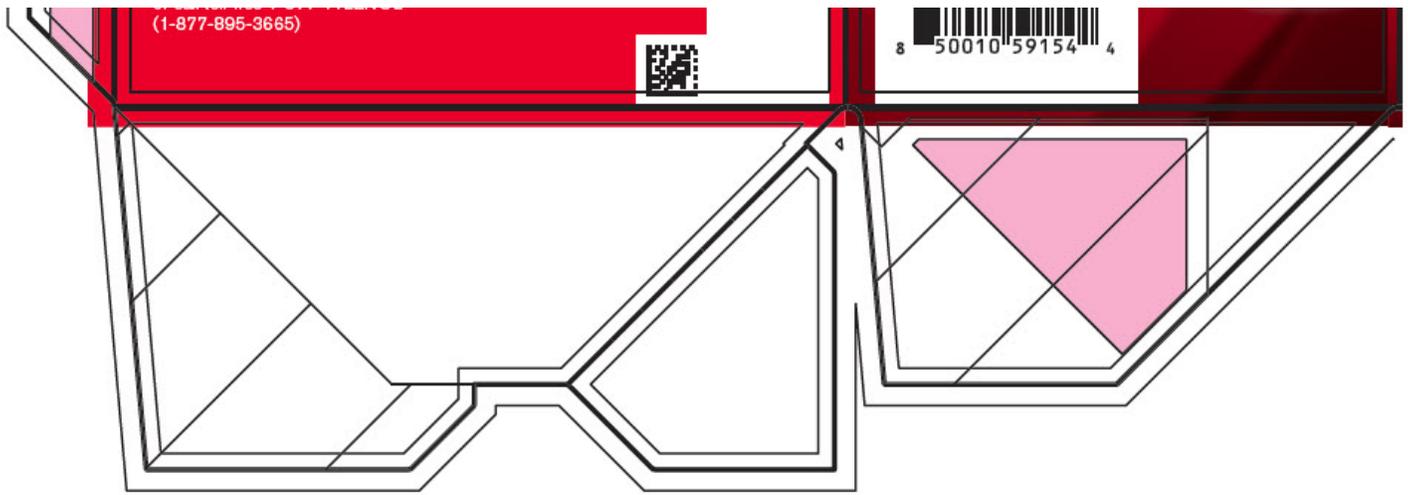
TYLENOL[®]
SINUS SEVERE
 FOR ADULTS

Acetaminophen, Phenylephrine HCl, Guafenesin
 Pain Reliever-Fever Reducer, Nasal Decongestant, Expectorant

Made in Italy
 Distributed by:
**JOHNSON & JOHNSON
 CONSUMER INC.**
 McNeil Consumer Healthcare Division
 Fort Washington, PA 19034 USA
 ©J&JCI 2021
 Visit us at www.tylenol.com
 or call toll-free 1-877-TYLENOL

Repackaged and distributed by:
 RJ General
 2024 Northwest Drive
 Cincinnati OH 45231





TYLENOL SINUS SEVERE

acetaminophen tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70264-026(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:1VS297W6MV)	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: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRACETIN (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:70264-026-02	50 in 1 BOX	05/01/2021	
1		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	05/01/2021	

Labeler - R J General Corporation (122542830)**Establishment**

Name	Address	ID/FEI	Business Operations
R J General Corporation		122542830	repack(70264-026)

Establishment

Name	Address	ID/FEI	Business Operations
Johnson & Johnson		878046358	manufacture(70264-026)

Revised: 10/2023

R J General Corporation