

TYLENOL SINUS SEVERE- acetaminophen, guaifenesin, phenylephrine hydrochloride tablet, coated
JC World Bell Wholesale Co., Inc.

Tylenol Sinus Severe

Drug Facts

Active ingredient (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

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 **Liver warning:**

acetaminophen may cause severe skin reactions. Symptoms may include: **Allergy alert:**

- 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
- 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.

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. **Overdose warning:**

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

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



Drug Facts

Active ingredients (in each caplet)

| | |
|------------------------|-----------------------------|
| 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:
- runny nose and sneezing
- nasal congestion and pressure
- throat irritation
- itchy eyes and nose
- itchy ears and nose
- itchy throat
- itchy skin
- itchy scalp
- itchy eyelids
- itchy lips
- itchy mouth
- itchy tongue
- itchy throat
- itchy nose
- itchy throat
- itchy nose
- itchy throat
- itchy nose
- itchy throat

Warnings

Clear warning: This product contains acetaminophen. The maximum daily dose of this product is 10 caplets (3250 mg acetaminophen) in 24 hours. Severe liver damage may occur if you take more than 10 caplets of acetaminophen in 24 hours.

Directions

Take 1 or 2 caplets every 4 to 6 hours as needed. Do not take more than 10 caplets in 24 hours.

Other information

Do not take if you are taking a prescription medicine that contains acetaminophen, aspirin, or salicylates.

Questions or comments?

Call 1-877-895-3665 (U.S. only) or 210-271-8750 (Canada).

TYLENOL[®] SINUS SEVERE FOR ADULTS
Acetaminophen, Phenylephrine HCl, Guaifenesin
Pain Reliever-Fever Reducer, Nasal Decongestant, Expectorant

Directions

Take 1 or 2 caplets every 4 to 6 hours as needed. Do not take more than 10 caplets in 24 hours.

Other information

Do not take if you are taking a prescription medicine that contains acetaminophen, aspirin, or salicylates.

TYLENOL[®] SINUS SEVERE FOR ADULTS
Acetaminophen, Phenylephrine HCl, Guaifenesin
Pain Reliever-Fever Reducer, Nasal Decongestant, Expectorant

DAY
Non-Drowsy

Actual Size

TO OPEN PUSH IN TAB AND PULL OUT

25 Pouches of 2 Caplets each

TYLENOL[®] SINUS SEVERE FOR ADULTS
Acetaminophen, Phenylephrine HCl, Guaifenesin
Pain Reliever-Fever Reducer, Nasal Decongestant, Expectorant

Actual Size

Made in Italy
Distributed by:
JOHNSON & JOHNSON CONSUMER INC.
McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
©J&JCI 2016
Visit us at www.tylenol.com
or call toll-free 1-877-TYLENOL
(1-877-895-3665)



Product repackaged and distributed with permission of the manufacturer by:
JC World Bell Wholesale Company, Inc. Hackensack, NJ 07601

TYLENOL SINUS SEVERE

acetaminophen, guaifenesin, phenylephrine hydrochloride tablet, coated

| Product Information | | | |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:50269-507(NDC:50580-507) |
| 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) | | |
| HYDROXYPROPYL CELLULOSE (70000 WAMW) (UNII: 6607AQVORT) | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | |
| MAGNESIUM STEARATE (UNII: 70097M6130) | | |
| 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:50269-507-25 | 25 in 1 BOX | 09/20/2018 | |
| 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 | 09/20/2018 | |

Labeler - JC World Bell Wholesale Co., Inc. (805257581)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------------|---------|-----------|---------------------|
| JC World Bell Wholesale Co., Inc. | | 805257581 | repack(50269-507) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------|---------|-----------|------------------------|
| Kenvue Brands LLC | | 878046358 | manufacture(50269-507) |

Revised: 12/2024

JC World Bell Wholesale Co., Inc.