

SINUS CONGESTION AND PAIN SEVERE- acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated
Wal-Mart Stores Inc

Equate 44-527C

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:
 - headache
 - minor aches and pains
 - nasal congestion
 - sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. 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:

- blisters
- rash
- skin reddening

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

- diabetes
- heart disease
- thyroid disease
- liver disease
- high blood pressure
- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- difficulty in urination due to enlargement of the prostate gland

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
- new symptoms occur
- 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.

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. Prompt 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**
- adults and children 12 years and over

- 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
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

corn starch, crospovidone, flavor, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

Questions or comments?

1-888-287-1915

Principal Display Panel

NDC 49035-527-08

equate[™]

Compare to Tylenol® SINUS SEVERE active ingredients*

**Daytime Non-Drowsy
Severe**

**Sinus Congestion
& Pain**

Acetaminophen- Pain Reliever/Fever Reducer

Guaifenesin- Expectorant

Phenylephrine HCl- Nasal Decongestant

Relieves:

- Sinus headache
- Sinus pressure
- Nasal congestion
- Mucus & chest congestion

**24
CAPLETS**

Actual Size

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS

**OPENED OR IF BLISTER UNIT IS TORN,
BROKEN OR SHOWS ANY SIGNS OF TAMPERING**

Satisfaction
guaranteed - For
questions
or comments
please call
1-888-287-1915

DISTRIBUTED BY: Walmart Inc., Bentonville, AR 72716

*This product is not manufactured or distributed by
Johnson & Johnson Corporation, owner of the registered
trademark Tylenol® Sinus Severe.
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Compare to Tylenol® Sinus Severe active ingredients*



DAYTIME

NON-DROWSY

SEVERE

Sinus Congestion & Pain

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CAPLETS

Drug Facts (continued)

■ helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive

Warnings

■ **Liver warning:** This product contains acetaminophen. 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:

- hives
- rash
- skin redness

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

Do not use

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Ask a doctor before use if you have

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- heart disease
- liver disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

Drug Facts (continued)

■ see end flap for expiration date and lot number

Inactive ingredients corn starch, croscarmellose, flavor, magnesium stearate, methocel, microcrystalline cellulose, polyethylene glycol, stearic acid, sucralose, titanium dioxide

Questions or comments? 1-888-287-1915

Drug Facts (continued)

■ 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

- redness or swelling is present
- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 7 days
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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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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Other information

- each caplet contains sodium 3 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTERS ARE TORN OR BROKEN
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Drug Facts (continued)

Uses

- temporarily relieves these symptoms associated with hay fever or other respiratory allergies, and the common cold:
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No Print/No Varnish
Lot and Expiration No.

Satisfaction guaranteed - For questions or comments please call 1-888-287-1915



PAPER BOX MULTI-LAYER TRAY

B-2203-527C-08-SC
REV0922M52708

Equate 44-527C

SINUS CONGESTION AND PAIN SEVERE

acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49035-527 |
| 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 |
|---|----------|
| STARCH, CORN (UNII: O8232NY3SJ) | |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MALTODEXTRIN (UNII: 7CVR7L4A2D) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990) | |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| SUCRALOSE (UNII: 96K6UQ3ZD4) | |
| TALC (UNII: 7SEV7J4R1U) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

Product Characteristics

| | | | |
|-----------------|---------|---------------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 19mm |
| Flavor | MENTHOL | Imprint Code | 44;527 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:49035-527-08 | 2 in 1 CARTON | 08/06/2005 | |
| 1 | | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | | |
| 2 | NDC:49035-527-42 | 12 in 1 BLISTER PACK; Type 0: Not a Combination Product | 08/06/2005 | 01/24/2023 |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012 | 08/06/2005 | |

Labeler - Wal-Mart Stores Inc (051957769)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|--|
| LNK International, Inc. | | 832867837 | manufacture(49035-527) , pack(49035-527) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 832867894 | manufacture(49035-527) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------------------|---------|-----------|------------------------|
| LNK International, Inc. | | 117025878 | manufacture(49035-527) |

Revised: 1/2024

Wal-Mart Stores Inc