

**SINUS CONGESTION AND PAIN SEVERE- acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated**

**ARMY AND AIR FORCE EXCHANGE SERVICE**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Exchange Select 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
  - nasal congestion
  - minor aches and pains
  - 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 in 24 hours, which is the maximum daily amount
- 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**

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- heart disease
- thyroid disease
- diabetes
- liver disease
- high blood pressure
- difficulty in urination due to an 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
- 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs of 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***

- **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, silicone dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

**Questions or comments?**

**1-800-426-9391**

**Principal Display Panel**

exchange select™

**Compare To  
The Active Ingredients of  
Tylenol® SINUS SEVERE\***

**Pseudoephedrine Free**

**SINUS  
SEVERE CONGESTION & PAIN**

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

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

**DAY  
NON-DROWSY**

Actual Size

**24 Caplets**

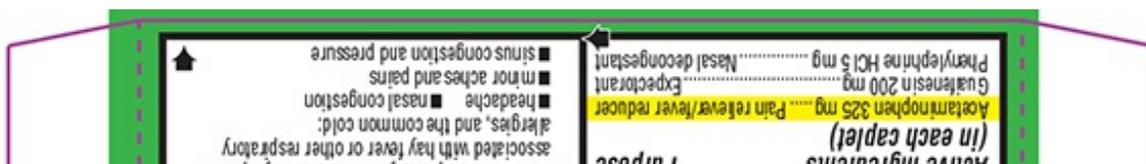
**TAMPER EVIDENT: DO NOT USE IF PACKAGE IS  
OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR  
SHOWS ANY SIGNS OF TAMPERING**

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol® SINUS SEVERE.

50844 REV0917E52708

**"SATISFACTION GUARANTEED OR YOUR MONEY BACK"**

Manufactured For Your Military Exchanges  
Distributed by: LNK International, Inc.  
Hauppauge, NY 11788 1-800-426-9391



exchange **select**

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# SINUS

## SEVERE CONGESTION & PAIN

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

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

DAY  
NON-DROWSY



Actual Size

24 Caplets

quality  
value

No print area  
Lot no. & Exp. Date

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**Drug Facts** (continued)  
KEEP OUT OF REACH OF CHILDREN  
COMPLETE PRODUCT INFORMATION

**Drug Facts**  
Active ingredients

**Drug Facts** (continued)

Questions or comments? 1-800-426-9391

TAMPER EVIDENT: DO NOT USE IF PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING



**Drug Facts** (continued)  
**Inactive ingredients** com starch, crospovidone, Flavor, magnesium stearate, maltoedextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucralose, talc, titanium dioxide

**Drug Facts** (continued)  
**Other information** ■ 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)  
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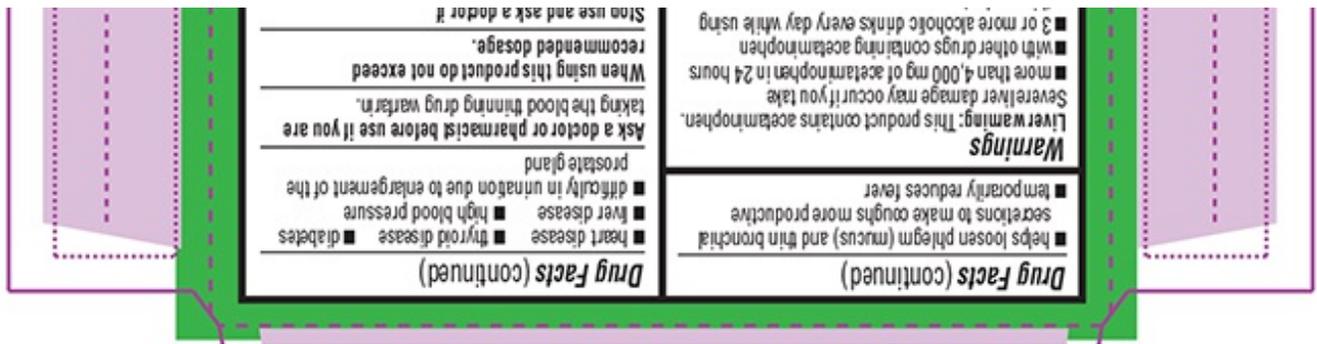
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■ swallow whole - do not crush, chew, or dissolve  
■ do not take more than 10 caplets in 24 hours  
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**Keep out of reach of children.** In case of accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.  
**If pregnant or breast-feeding,** ask a health professional before use.  
■ pain, nasal congestion, or cough gets worse or lasts more than 7 days  
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■ new symptoms occur  
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■ 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**  
■ cough that occurs with too much phlegm (mucus) persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema  
**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.

No Print  
Glue Area

No Print  
Glue Area

B-0066E-527C-08-SS  
REV0917E52708



Exchange Select 44-527C

## SINUS CONGESTION AND PAIN SEVERE

acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:55301-527 |
| <b>Route of Administration</b> | 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 |
|--|----------|
| MAGNESIUM STEARATE (UNII: 70097M6I30)                    |          |
| MALTO DEXTRIN (UNII: 7CVR7L4A2D)                         |          |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)            |          |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)      |          |
| POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)                 |          |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4)                       |          |
| SUCRALOSE (UNII: 96K6UQ3ZD4)                             |          |
| TALC (UNII: 7SEV7J4R1U)                                  |          |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP)                      |          |
| STARCH, CORN (UNII: O8232NY3SJ)                          |          |
| CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)              |          |
| STEARIC ACID (UNII: 4ELV7Z65AP)                          |          |
| POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)        |          |
| SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2) |          |

### Product Characteristics

|              |       |              |          |
|--------------|-------|--------------|----------|
| <b>Color</b> | WHITE | <b>Score</b> | no score |
|--------------|-------|--------------|----------|

|                 |      |                     |        |
|-----------------|------|---------------------|--------|
| <b>Shape</b>    | OVAL | <b>Size</b>         | 19 mm  |
| <b>Flavor</b>   | MINT | <b>Imprint Code</b> | 44;527 |
| <b>Contains</b> |      |                     |        |

### Packaging

| # | Item Code        | Package Description                                     | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55301-527-08 | 2 in 1 CARTON   | 08/06/2005           |                    |
| 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 FINAL | part341                                  | 08/06/2005           |                    |

**Labeler** - ARMY AND AIR FORCE EXCHANGE SERVICE (001695568)

### Establishment

| Name                    | Address | ID/FEI    | Business Operations     |
|-------------------------|---------|-----------|-------------------------|
| LNK International, Inc. |         | 832867894 | MANUFACTURE(5530 1-527) |

### Establishment

| Name                    | Address | ID/FEI    | Business Operations |
|-------------------------|---------|-----------|---------------------|
| LNK International, Inc. |         | 832867837 | PACK(5530 1-527)    |

Revised: 6/2019

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