

**SEVERE SINUS CONGESTION AND PAIN DAYTIME- acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated  
GREENBRIER INTERNATIONAL, INC.**

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**Assured 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 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**

- 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 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 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***

- **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°C-30°C (59°F-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?***

**1-800-426-9391**

### **Principal Display Panel**

**ASSURED™**

**COMPARE TO** ACTIVE INGREDIENTS OF **TYLENOL® SINUS SEVERE\***

**DAYTIME  
NON-DROWSY**

**SEVERE  
SINUS  
CONGESTION & PAIN**

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

***Headache, Sinus Pressure,  
Nasal Congestion, Fever  
& Chest Congestion***

Actual Size

**PSEUDOEPHEDRINE FREE**

**12 caplets  
with Cool Blast Flavor**

**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          REV0917H52702

ITEM# 10684

Distributed by:

**Greenbrier International, Inc.**

Chesapeake, VA 23320 USA

**Drug Facts** (continued)

**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

**Drug Facts** (continued)

**Active ingredients** (in each caplet)  
 Acetaminophen 325 mg ..... Pain reliever/fever reducer  
 Guaifenesin 200 mg ..... Expectorant  
 Phenylephrine HCl 5 mg ..... Nasal decongestant

**Purpose**  
 COMPLETE PRODUCT INFORMATION  
 KEEP OUTER PACKAGE FOR

COMPARE TO ACTIVE INGREDIENTS OF  
 TYLENOL® SINUS SEVERE\*

**ASSURED**

**SEVERE**

**SINUS CONGESTION & PAIN**

**DAYTIME NON-DROWSY**

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



Actual Size  
 PSEUDOEPHEDRINE FREE

**Headache, Sinus Pressure,  
 Nasal Congestion, Fever  
 & Chest Congestion**

**12 caplets**  
 with Cool Blast Flavor



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

no print / no varnish area  
 lot no. & exp. date

**Drug Facts** (continued)  
 Questions or comments? 1-800-426-9391

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Distributed by:  
**Greenbrier International, Inc.**  
 Chesapeake, VA 23320 USA

**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)  
 ■ see end flap for expiration date and lot number

**Drug Facts** (continued)

**Inactive ingredients** corn starch, croscopolone, flavin, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, sucrose, talc, titanium dioxide

**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) or persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**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

**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.

■ cough comes back or occurs with rash or headache that lasts. These could be signs of a serious condition.

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B-0316-527C-02SCR  
 REV0917H52702



Assured 44-527C

## SEVERE SINUS CONGESTION AND PAIN DAYTIME

acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:33992-0527
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>CROSPVIDONE, UNSPECIFIED</b> (UNII: 2S7830E561)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	19mm
<b>Flavor</b>	MENTHOL	<b>Imprint Code</b>	44;527
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:33992-0527-2	1 in 1 CARTON	08/06/2005	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:33992-0527-8	2 in 1 CARTON	08/06/2005	07/08/2018
2		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 Drug	M012	08/06/2005	

**Labeler** - GREENBRIER INTERNATIONAL, INC. (610322518)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(33992-0527) , pack(33992-0527)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(33992-0527)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(33992-0527)

Revised: 11/2023

GREENBRIER INTERNATIONAL, INC.