## SEVERE SINUS CONGESTION AND PAIN NON-DROWSY, DAYTIME- acetaminophen, guaifenes in and phenylephrine hcl tablet, film coated Valu Merchandisers Company

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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#### **Best Choice 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:
  - minor aches and pains
  - nasal congestion
  - sinus congestion and pressure
  - headache
- 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

- liver disease
- thyroid disease
- diabetes
- heart disease
- high blood pressure
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)
- 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°-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?** 

1-800-426-9391

**Principal Display Panel** 

Best Choice®

COMPARE TO THE ACTIVE INGREDIENTS IN TYLENOL® SINUS SEVERE\*

Non-Drowsy Severe Daytime SINUS Congestion & Pain

ACETAMINOPHEN - Pain Reliever / Fever Reducer Guaifenes in - Expectorant Phenylephrine HCI - Nasal Decongestant

Relieves Headache, Fever, Chest Congestion, Sinus Pressure, Nasal Congestion

#### Pseudoephedrine Free

Actual Size

24 Cool Caplets with Cool Blast Flavor

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Tylenol $^{\mathbb{R}}$  SINUS SEVERE.

50844 REV0917G52708

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

PROUDLY DISTRIBUTED BY: VALU MERCHANDISERS, CO. 5000 KANSAS AVE KANSAS CITY, KS 66106

Best Choice<sub>®</sub>
100% Guaranteed

www.bestchoicebrand.com

 sinus congestion and pressure uninor aches and pains ■ pesqueche = nassi congestion

silergies, and the common cold: associated with hay fever or other respiratory ■ temporarily relieves these symptoms

Urug Facts (continued)

Masal decongestant Phenylephine HCl 5 mg instolosqua... Gm 00S nisənəlisu 2 Pain reliever/fever reducer cetaminophen 325 mg

(in each capiet) Active ingredients

COMPLETE PRODUCT INFORMATIO KEEP OUTER PACKAGE FOR

Purpose

Drug Facts

COMPARE TO THE ACTIVE INGREDIENTS INTYLENOL® SINUS SEVERE\*

Best

Actual Size

Non-Drowsy

# Daytime

Congestion & Pain

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Best Choice, 00% Guaranteed

No print/No varnish Lot & Exp date

0 BEST CHOICE  $\infty$ œ

polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearica sucralose, talc, titanium dioxide

stearicacid

Questions or comments? 1-800-426-9391

Drug Facts (continued

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BLISTER IS TORN OR BROKEN DO NOT USE IF OUTER PACKAGE IS OPENED OR Other information = TAMPER EVIDENT:

**Nung Facts** (continued)

B-2115-527C-08-SCF REV0917G52708

children under 12 years: ask a doctor

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Best Choice 44-527C

#### SEVERE SINUS CONGESTION AND PAIN NON-DROWSY, DAYTIME

acetaminophen, guaifenesin and phenylephrine hcl tablet, film coated

<b>Product Information</b>			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63941-527
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
ACETAMINO PHEN (UNII: 36209 ITL9 D) (ACETAMINO PHEN - UNII: 36209 ITL9 D)	ACETAMINOPHEN	325 mg		
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg		
PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg		

Inactive Ingredients	
Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
PO VIDO NE (UNII: FZ989 GH9 4E)	
CROSPOVIDONE (UNII: 2S7830E561)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics				
Color	WHITE	Score	no score	
Shape	OVAL	Size	19 mm	
Flavor	MINT	Imprint Code	44;527	
Contains				

l	Packaging				
l	# Item Code	Package Description	<b>Marketing Start Date</b>	Marketing End Date	
l	1 NDC:63941-527-08	2 in 1 CARTON	08/06/2005		
ı	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 - Valu Merchandisers Company (868703513)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(63941-527)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(63941-527)

Revised: 11/2019 Valu Merchandisers Company