

**SINUS CONGESTION AND PAIN RELIEF- acetaminophen, guaifenesin and phenylephrine hcl  
325 mg, 200 mg and 5 mg tablet, coated**

**We Care Distributor Inc.**

*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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**SINUS CONGESTION AND PAIN RELIEF - Acetaminophen, Guaifenesinand Phenylephrine  
HCl**

***Drug Facts***

Active Ingredient (in each tablet)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

**Uses**

- for the temporary relief of:
- 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 relieves nasal congestion due to the common cold and hay fever and other upper respiratory allergies
- temporarily reduces fever

**Warnings**

**Liver warning:**

This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg acetaminophen) in 24 hours. 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

**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 monomine 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

- thyroid disease
- diabetes
- high blood pressure
- persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema
- trouble urinating due to an enlarged prostate gland
- 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**

- 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
- new symptoms occur
- 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.**

**Overdose Warning:** Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick 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 (see overdose warning)**
- **adults and children 12 years and over:**
- take 2 tablets every 4 hours
- swallow whole - do not crush, chew or dissolve
- do not take more than 10 tablets in 24 hours
- **children under 12 years:** ask a doctor

**Other information**

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- read all product information before using. Keep this box for important information

**Inactive ingredients**

FD&C red #40, maltodextrin, microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

**Questions or comments?**

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or [www.wecaredistributor.com](http://www.wecaredistributor.com)

# PRINCIPAL DISPLAY PANEL

## See New Warnings Information & Directions

## Compare to the Active Ingredients in

## Tylenol® Sinus Congestion & Pain Severe

## Acetaminophen, Guaifenesin and Phenylephrine HCl 325 mg, 200 mg and 5 mg

### TO OPEN

### PUSH IN TAB AND PULL OUT

### 25 Pouches of 2 Tablets Each

NDC: 70005-012-25



# SINUS RELIEF

COMPARE TO

# Tylenol®

SINUS CONGESTION & PAIN SEVERE ACTIVE INGREDIENTS\*

Acetaminophen, 325 mg  
Guaifenesin, 200 mg  
Phenylephrine HCl, 5 mg

**SEVERE SINUS CONGESTION & PAIN**  
Pain Reliever, Fever Reducer,  
Expectorant, Nasal Decongestant  
• Daytime • Non-Drowsy • For Adults

\*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Tylenol® Sinus Congestion & Pain Severe.

25 Pouches of 2 Coated Tablets

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**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  thyroid disease  diabetes  high blood pressure  persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema  trouble urinating due to an enlarged prostate gland  cough that occurs with too much phlegm (mucus)

**Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.**

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### Drug Facts (continued)

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**Inactive ingredients** FD-C red #40, maltodextrin, microcrystalline cellulose, sodium starch glycolate, stearic acid, starch, pladone

**Questions or comments?**  
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**DO NOT USE IF POUCH IS BROKEN OR TORN**

Manufactured For / Distributed By:  
We Care Distributor Inc.  
Hermitage, TN 37078  
www.wecaredistributor.com

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**Ask a doctor before use if you have:** liver disease, heart disease, thyroid disease, diabetes, high blood pressure, persistent or chronic cough as occurs with smoking, asthma, chronic bronchitis, or emphysema, trouble urinating due to an enlarged prostate gland, or cough that occurs with too much phlegm (mucus).

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### Questions or comments?

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## SINUS CONGESTION AND PAIN RELIEF

acetaminophen, guaifenesin and phenylephrine hcl 325 mg, 200 mg and 5 mg tablet, coated

### Product Information

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:70005-012

**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	5 mg

## Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE (UNII: FZ989GH94E)	

## Product Characteristics

Color	pink	Score	no score
Shape	OVAL	Size	12mm
Flavor		Imprint Code	FR;14
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-012-25	25 in 1 BOX	02/15/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-012-50	50 in 1 BOX	02/15/2016	
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-012-02	2 in 1 POUCH	02/15/2016	
3		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 not final	part343	02/15/2016	

**Labeler** - We Care Distributor Inc. (079832998)

## Establishment

Name	Address	ID/FEI	Business Operations
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Revised: 10/2019

We Care Distributor Inc.