

**SOHMED SINUS- acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet**  
**Sohm 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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**SohMed™ Sinus**

***Drug Facts***

<b><i>Active ingredients (in each caplet)</i></b>	<b><i>purpose</i></b>
Acetaminophen 325 mg	Pain reliever
Guaifenesin 200mg	Expectorant
Phenylephrine HCL 5mg	Nasal decongestant

**Uses**

- for the temporary relief of :
  - sinus congestion and pressure
  - headache
  - nasal congestion
  - minor aches and pains
  - helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive
- temporarily relieves nasal congestion due to the common cold, and hay fever and other upper respiratory allergies

**Warnings**

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 8 caplets 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.

Although rare, possible reactions to consumption of acetaminophen include three serious skin diseases whose symptoms can include rash, blisters and, in the worst case, widespread damage to the surface of the skin. If you are taking this product and develop a rash or other skin reaction, stop taking this product immediately and seek medical attention.

**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

- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- 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 for more than 7 days
  - fever gets worse or lasts for 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.**

**Overdose warning**

In case of overdose, get medical help or contact a PoisonControl 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**

- adults and children 12 years and over
  - take 1-2 caplets every 4 hours as needed
  - do not take more than 8 caplets in 24 hours
- children under 12 years
  - consult a doctor

**Other information**

- avoid excessive heat and humidity store between 15°-30°C (59°-86°f)
- See end flap for expiration date and lot number

**Inactive ingredients**

Colloidal silicon dioxide, sodium lauryl sulphate, edetate disodium, dioctyl sodium sulphosuccinate, polyvinyl pyrrolidone, gelatin, corn starch, magnesium stearate, microcrystalline cellulose, polyethylene glycol 6000, sodium benzoate, sodium starch glycolate, stearic acid, purified talc, titanium dioxide

**Question or comments?**

1(856) 2863646

**Distributed by : Sohm, Inc.**  
6920 Knott Ave., Suit A-C,

Buena Park, CA 90621

**PRINCIPAL DISPLAY PANEL - 24 Caplet Bottle Carton**

**SohMed™**

**NDC XXXXXXXXXX**

**\*Compare to the active ingredients in Tylenol® Sinus Congestion  
& Pain Severe Day Time**

**SEVERE**

***Sinus Congestion & Pain Relief***

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

***Relieves Sinus Pressure, Nasal Congestion and Fever***

**24 Caplets**

**Daytime**

***Non-Drowsy***

**RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION**

## Drug Facts

### Active ingredients (in each caplet) purpose

Acetaminophen 325 mg..... Pain reliever  
Guaifenesin 200mg..... Expectorant  
Pseudoephedrine HCl 5mg..... Nasal decongestant

**Uses** • for the temporary relief of: • sinus congestion and pressure • headache • nasal congestion • minor aches and pains • helps loosen phlegm (mucus) and thin bronchial secretions to make cough more productive • temporarily relieves nasal congestion due to the common cold, and hay fever and other upper respiratory allergies

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### Drug Facts (continued)

**Ask a doctor before use if you have** • liver disease • heart disease • high blood pressure • thyroid disease • diabetes • trouble urinating due to an enlarged prostate gland • persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema • 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 for more than 7 days • fever gets worse or lasts for 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.

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• adults and children 12 years and over  
• take 1-2 caplets every 4 hours as needed • do not take more than 8 caplets in 24 hours  
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### Drug Facts (continued)

#### Other information

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#### Question or comments?

1 (856) 2863646

\*This Product is not manufactured or distributed by McNeil Consumer Healthcare, owner of registered trademark Tylenol<sup>®</sup> sinus Congestion & Pain Sever Daytime.

**Distributed by: Sohm, Inc.**

6920 Knott Ave., Suit A-C,  
Buena Park, CA 90621



www.sohm.com

NDC XXXXXXXXXX



\*Compare to the active ingredients in Tylenol® Sinus Congestion & Pain Severe Day Time

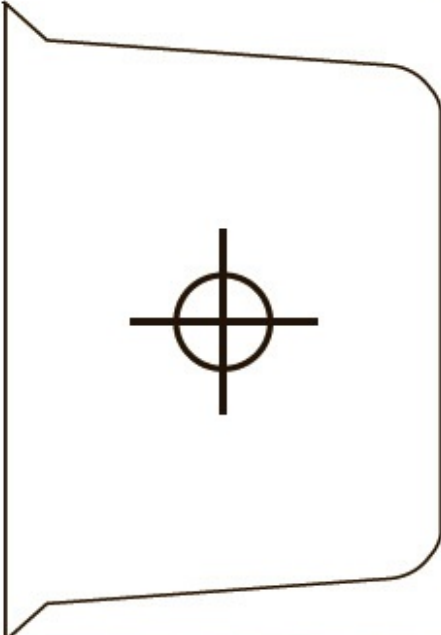
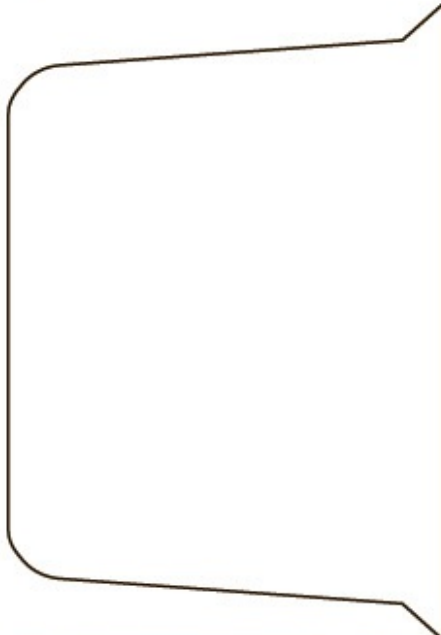
# SEVERE Sinus Congestion & Pain Relief

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

Relieves Sinus Pressure, Nasal Congestion and Fever

24 Caplets

Daytime Non-Drowsy

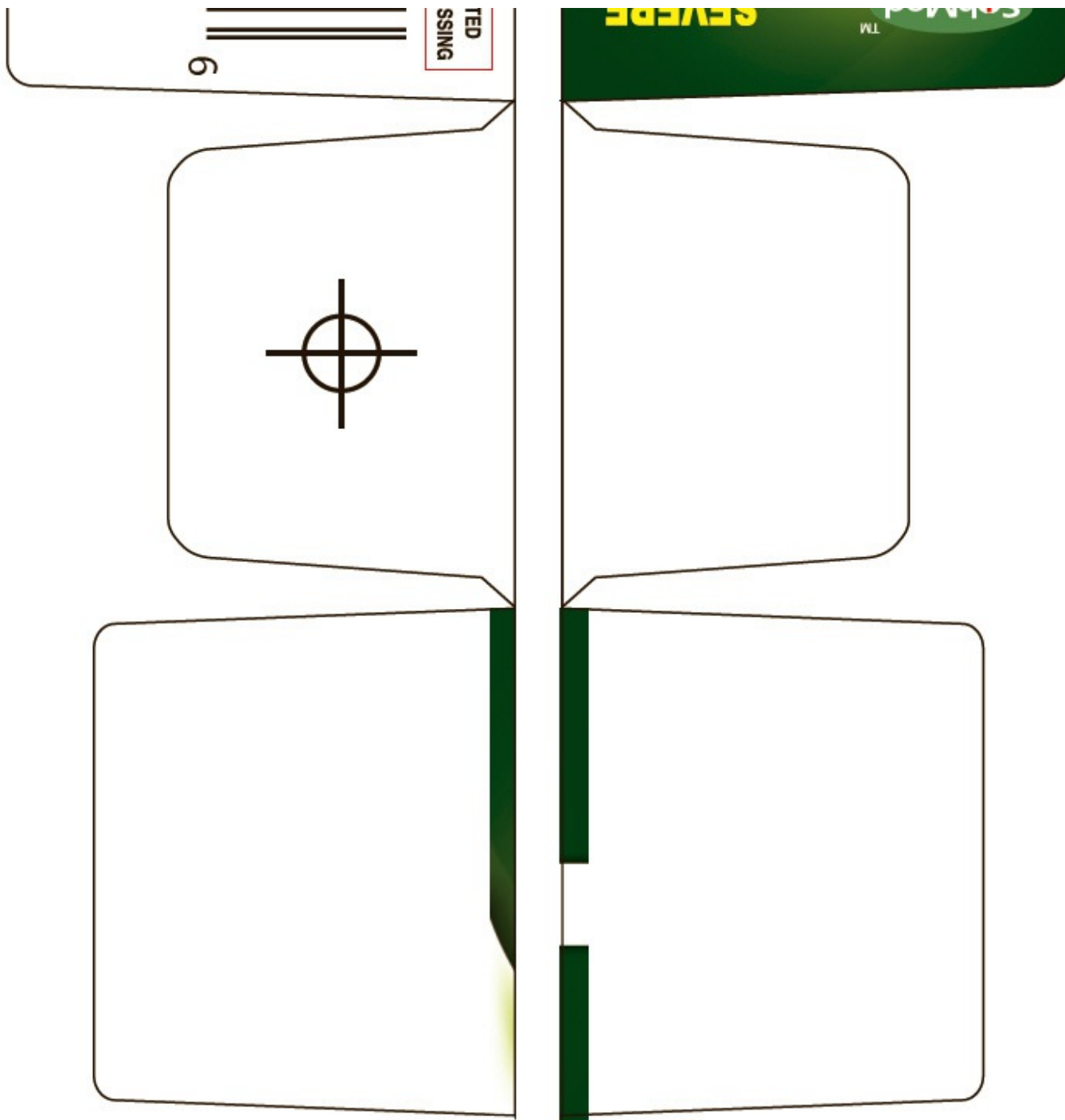


TAMPER EVIDENT: DO NOT USE IF IMPRINT SAFETY SEAL UNDER CAP IS BROKEN OR MISSING



LOT NO.

EXP.



## SOHMED SINUS

acetaminophen, guaifenesin, and phenylephrine hydrochloride tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50405-009
<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

<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>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>DI-2-HEXYL SODIUM SULFO SUCCINATE</b> (UNII: 772Y8KZU65)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE K90</b> (UNII: RDH86HJV5Z)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OPIR32D61U)	
<b>POLYETHYLENE GLYCOL 6000</b> (UNII: 30IQX730WE)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	WHITE	<b>Score</b>	2 pieces
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	CRX
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50405-009-24	1 in 1 CARTON		
1		24 in 1 BOTTLE, PLASTIC		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	08/25/2013	

**Labeler** - Sohm Inc. (009303848)