SOHMED ALLERGY SINUS- acetaminophen, chlorpheniramine maleate, and phenylephrine hcl 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.

SohMed™ Allergy Sinus

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever
Chlorpheniramine maleate 2 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these symptoms of hay fever or other upper respiratory allergies :
  - headache
  - sinus congestion and pressure
  - nasal congestion
  - itchy, watery eyes
  - runny nose and sneezing
  - minor aches and pains
  - itching of the nose or throat
  - helps decongest sinus openings and passages

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 everyday 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, pscychiatric 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
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not exceed recommended dosage**
- excitability may occur, especially in children
- drowsiness may occur
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion 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

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 over-dose, get medical help or contact a Poison Control 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

do not take more than directed (see overdose warning)

- adults and children 12 years and over
  - take 2 caplets every 4 hours
  - 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, polyvinylpyrollidone, gelatin, corn starch, magnesium stearate, microcrystalline cellulose, polyethylene glycol 6000, sodium benzoate, sodium starch glycolate, stearic acid, purified talc, titanium dioxide, yellow iron oxide.

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

NDC XXXXXXXXXX

SohMed™
Compare to the active ingredients in Tylenol:: Allergy Multi-symptom

Multi-Symptom

Allergy Sinus

Acetaminophen *325 mg*
Chlorpheniramine maleate *2 mg*
Phenylephrine HCl *5 mg*

• Sneezing • Runny Nose • Congestion

24 Caplets

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

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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 • a breathing problem such as emphysema or chronic bronchitis • glaucoma

Ask a doctor or pharmacist before use if you are • taking the blood thinning drug warfarin • taking sedatives or tranquilizers
When using this product • do not exceed recommended dosage • excitability may occur, especially in children • drowsiness may occur • alcohol, sedatives and tranquilizers may increase drowsiness • avoid alcoholic drinks • be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if • nervousness, dizziness, or sleeplessness occur • pain or nasal congestion 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 These could be signs of a serious condition. If pregnant or breast-feeding, ask a health professional before use.

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Question or comments?

1(856) 2863646

*This Product is not manufactured or distributed McNeil Consumer Healthcare, distributor of Tylenol® Allergy Multi-symptom.

Distributed by : **Sohm, Inc.**
6920 Knott Ave., Suit A-C,
Buena Park, CA 90621

SohMed™

www.sohm.com

NDC XXXXXXXXXX

SohMed™

*Compare to the active ingredients in Tylenol® Allergy Multi-symptom

Multi-Symptom

Allergy Sinus

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Chlorpheniramine maleate 2 mg
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• Sneezing • Runny Nose • Congestion

24 Caplets

SOHMED ALLERGY SINUS

acetaminophen, chlorpheniramine maleate, and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:50405-003
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Chlorpheniramine maleate (UNII: V1Q0O9OJ9Z) (Chlorpheniramine - UNII:3U6IO1965U)	Chlorpheniramine maleate	2 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DOCUSATE SODIUM (UNII: F05Q2T2JA0)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
GELATIN (UNII: 2G86QN327L)	
STARCH, CORN (UNII: O8232NY3SJ)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 6000 (UNII: 30IQX730WE)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	YELLOW	**Score**	2 pieces
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	CRX
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50405-003-24	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)

Revised: 8/2013 SOHM Inc.