

SOHMED COLD RELIEF- acetaminophen, dextromethorphan hydrobromide, 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.

SohMed™ Cold Relief

Drug Facts

Active ingredients (in each caplet)	Purpose
Acetaminophen 325 mg	Pain reliever
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- for the temporary relief of the following cold symptoms
- minor aches and pain
- headache
- sore throat
- nasal congestion
- cough
- sinus congestion and pressure
- helps loosen phlegm (mucus) and thin bronchial secretions to make coughs more productive.

Warnings

Liver warning

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

- more than 12 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

Sore throat warning : if sore throat is severe, persists, for more than 2 days, is accompanied or followed by fever, headache, rash, nausea or vomiting, consult a doctor promptly.

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 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.

Overdose warning

In case of overdose, 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 with water every 6-8 hours as needed
 - do not take more than 8 caplets in 24 hours
- children under 12 years
 - consult a doctor

Other information

- store between 20°-25°C (68°- 77°F)
- avoid excessive heat and humidity
- See and 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, D&C yellow# 10 aluminium lake, titanium dioxide.

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Question or comments?

1(856) 2863646

Distributed by : Sohm, Inc.

6920 Knott Ave., Suit A-C,

Buena Park, CA 90621

PRINCIPAL DISPLAY PANEL - 24 Tablet Bottle Carton

NDC XXXXXXXXXXXXX

SohMed™

***Compare to the active ingredients in Tylenol® Cold Head Congestion Severe**

Cold Relief

**Acetaminophen 325mg, Dextromethorphan HBr 10mg,
Guaifenesin 200mg, Phenylephrine HCl 5mg**

24 Caplets

**Pain Reliever, Fever Reducer,
Nasal Decongestant,
Cough Suppressant, expectorant**



SOHMED COLD RELIEF			
acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50405-006

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 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)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K90 (UNII: RDH86HJV5Z)	
GELATIN (UNII: 2G86QN327L)	
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)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LM26O6933)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:50405-006-24	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.