SEVERE SINUS CONGESTION RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled PuraCap Pharmaceutical LLC

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.

Severe Congestion Relief

Active ingredients (in each softgel)

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg Guaifenesin 200 mg Phenylephrine HCl 5 mg

Purpose

Pain reliever

Cough suppressant Expectorant Nasal decongestant

Uses

- temporarily relieves:
- nasal congestion
- headache
- minor aches and pains
- sinus congestion and pressure
- cough
- temporarily promotes nasal and/or sinus drainage
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

Warnings

Liver warning

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

- more than 12 liquid gels in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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.

Ask a doctor before use if you have

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to 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 use more than directed

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:

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center 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)
- do not take more than 12 liquid gels in any 24-hour period
- adults and children 12 years of age and older: take 2 liquid gels every 4 hours

• children under 12 years of age: do not use

Other information

- store between 15-30°C (59-86°F)
- avoid excessive heat

Inactive ingredients

FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution, and white edible ink

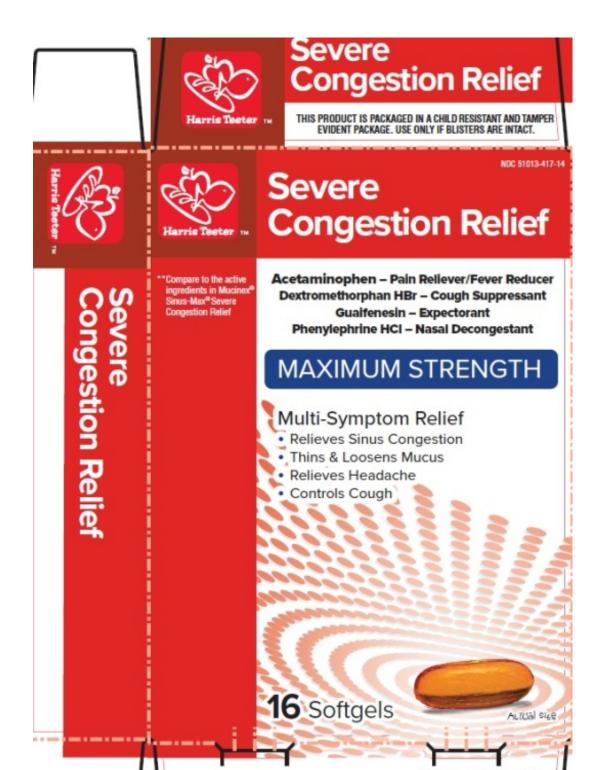
Questions or Comments?

Call toll free: 1-800-719-9260

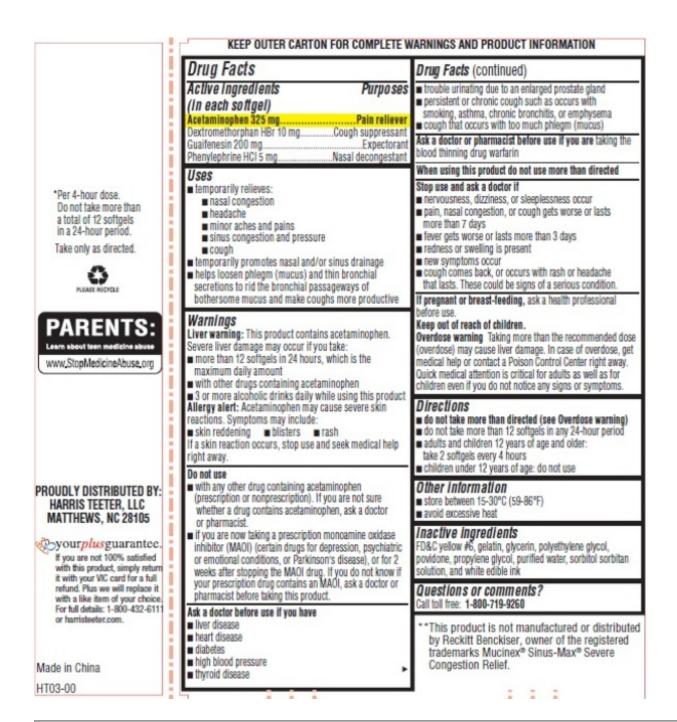
PRINCIPLE DISPLAY PANEL

Severe Congestion Relief 16 SOFTGELS

^{*}Compare to the active ingredients in Mucinex[®] Sinus-Max[®] Severe Congestion Relief



LOT NO: EXP DATE:



SEVERE SINUS CONGESTION RELIEF

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51013-417
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
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

PHENYLEPHRINE HYDRO CHLO RIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -	
UNII:1WS297W6MV)	

PHENYLEPHRINE HYDROCHLORIDE

5 mg

Inactive Ingredients		
Ingredient Name	Strength	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)		
GELATIN (UNII: 2G86QN327L)		
GLYCERIN (UNII: PDC6A3C0OX)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PO VIDO NE (UNII: FZ989 GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
SORBITOL (UNII: 506T60A25R)		
SORBITAN (UNII: 6O92ICV9RU)		
WATER (UNII: 059QF0KO0R)		

Product Characteristics			
Color	orange (Clear)	Score	no score
Shape	capsule (Oblong)	Size	25mm
Flavor		Imprint Code	PC26
Contains			

	Packaging			
ı	# Item Code	Package Description	Marketing Start Date	Marketing End Date
ı	1 NDC:51013-417-14	2 in 1 CARTON	08/29/2017	
ı	1	8 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	08/29/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment			
Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceuticals (Wuhan) Co., Ltd		421293287	manufacture(51013-417), analysis(51013-417)

Revised: 11/2019 PuraCap Pharmaceutical LLC