

**COLD FLU AND SORE THROAT 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.*

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**COLD, FLU & SORE THROAT RELIEF**

**Drug Facts**

**Active Ingredients (in each softgel)**

Acetaminophen 325 mg

Dextromethorphan HBr 10 mg

Guaifenesin 200 mg

Phenylephrine HCl 5 mg

**Purposes**

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

**Uses**

- temporarily relieves:
  - nasal congestion
  - headache
  - cough
  - minor aches and pains
  - sore throat
- temporarily reduces fever
- 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 softgels 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.

### **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.

### **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 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 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**

COLD, FLU & SORE THROAT 16 SOFTGELS

\*Compare to the active ingredients in Mucinex<sup>®</sup> Fast-Max<sup>®</sup> Cold, Flu & Sore Throat



# Cold, Flu & Sore Throat

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

NDC 51013-415-14



# Cold, Flu & Sore Throat

Cold, Flu & Sore Throat

\*\*Compare to the active ingredients in Mucinex® Fast-Max® Cold, Flu & Sore Throat

**Acetaminophen – Pain Reliever/Fever Reducer**  
**Dextromethorphan HBr – Cough Suppressant**  
**Guaifenesin – Expectorant**  
**Phenylephrine HCl – Nasal Decongestant**

**MAXIMUM STRENGTH**

### Multi-Symptom Relief

- Controls Cough, Thins & Loosens Mucus
- Relieves Nasal & Chest Congestion
- Relieves Headache & Fever

**16** Softgels



Adult Size

LOT NO:  
EXP DATE:



0 72036 72774 9

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>	
<b>Active Ingredients (In each softgel)</b>	<b>Purposes</b>	<ul style="list-style-type: none"> <li>trouble urinating due to an enlarged prostate gland</li> <li>persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema</li> <li>cough that occurs with too much phlegm (mucus)</li> </ul>	
Acetaminophen 325 mg.....	Pain reliever/fever reducer	<b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin</b>	
Dextromethorphan HBr 10 mg.....	Cough suppressant	<b>When using this product do not use more than directed</b>	
Guaifenesin 200 mg.....	Expectorant	<b>Stop use and ask a doctor if</b>	
Phenylephrine HCl 5 mg.....	Nasal decongestant	<ul style="list-style-type: none"> <li>nervousness, dizziness, or sleeplessness occur</li> <li>pain, nasal congestion, or cough gets worse or lasts more than 7 days</li> <li>fever gets worse or lasts more than 3 days</li> <li>redness or swelling is present</li> <li>new symptoms occur</li> <li>cough comes back, or occurs with rash or headache that lasts. These could be signs of a serious condition.</li> </ul>	
<b>Uses</b>		<b>If pregnant or breast-feeding, ask a health professional before use.</b>	
<ul style="list-style-type: none"> <li>temporarily relieves these common cold and flu symptoms:                             <ul style="list-style-type: none"> <li>headache</li> <li>nasal congestion</li> <li>minor aches and pains</li> <li>cough</li> <li>sore throat</li> </ul> </li> <li>temporarily reduces fever</li> <li>helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive</li> </ul>		<b>Keep out of reach of children.</b>	
<b>Warnings</b>		<b>Overdose warning</b> 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.	
<p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> <li>more than 12 softgels in 24 hours, which is the maximum daily amount</li> <li>with other drugs containing acetaminophen</li> <li>3 or more alcoholic drinks daily while using this product</li> </ul> <p><b>Allergy alert:</b> Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> <li>skin reddening</li> <li>blisters</li> <li>rash</li> </ul> <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p><b>Sore throat warning:</b> 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.</p>		<b>Directions</b>	
<b>Do not use</b>		<ul style="list-style-type: none"> <li>do not take more than directed (see Overdose warning)</li> <li>do not take more than 12 softgels in any 24-hour period</li> <li>adults and children 12 years of age and older: take 2 softgels every 4 hours</li> <li>children under 12 years of age: do not use</li> </ul>	
<ul style="list-style-type: none"> <li>with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>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.</li> </ul>		<b>Other information</b>	
<b>Ask a doctor before use if you have</b>		<ul style="list-style-type: none"> <li>store between 15-30°C (59-86°F)</li> <li>avoid excessive heat</li> </ul>	
<ul style="list-style-type: none"> <li>liver disease</li> <li>heart disease</li> <li>diabetes</li> <li>high blood pressure</li> <li>thyroid disease</li> </ul>		<b>Inactive Ingredients</b>	
		FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution and white edible ink	
		<b>Questions or comments?</b>	
		Call toll free: 1-800-719-9260	
		**This product is not manufactured or distributed by Reckitt Benckiser, owner of the registered trademarks Mucinex® Fast-Max® Cold, Flu & Sore Throat.	

## COLD FLU AND SORE THROAT RELIEF

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:510 13-415
<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
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
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

### Product Characteristics

Color	orange (clear)	Score	no score
Shape	capsule (oblong)	Size	25mm
Flavor		Imprint Code	PC26
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:510 13-415-14	2 in 1 CARTON	08/29/2017	
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 Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(510 13-415) , analysis(510 13-415)

Revised: 11/2019

PuraCap Pharmaceutical LLC