

**COLD FLU AND SORE THROAT RELIEF- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled**  
**Pharmacy Value Alliance, 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 20-25°C (68-77°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**

**PRINCIPAL DISPLAY PANEL - Carton Label**

**COLD, FLU & SORE THROAT RELIEF 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 68016-147-16

\*\*COMPARE TO THE ACTIVE INGREDIENTS IN MUCINEX® FAST-MAX® COLD, FLU & SORE THROAT



MAXIMUM STRENGTH

# Cold, Flu & Sore Throat

**MULTI-SYMPTOM RELIEF**

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

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



Actual Size

**16** Softgels



**Cold, Flu & Sore Throat**

LOT NO:  
EXP DATE:



8 40986 03459 6

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

\*Per 4-hour dose.  
Do not take more than a total of 12 softgels in a 24-hour period.  
Take only as directed.



**PARENTS:**

Learn about teen medicine abuse  
[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)



If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Distributed By:  
Pharmacy Value Alliance, LLC  
407 East Lancaster Avenue,  
Wayne, PA 19087

MADE IN CHINA  
PN XXXXXXX

PRE01-00

**Drug Facts**

**Active ingredients (in each softgel)**

Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Guaifenesin 200 mg.....	Expectorant
Phenylephrine HCl 5 mg.....	Nasal decongestant

**Uses**

- temporarily relieves these common cold and flu symptoms:
  - 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

**Drug Facts (continued)**

- 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**

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- pain, nasal congestion, or cough gets worse or lasts more than 7 days
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**Directions**

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- do not take more than 12 softgels in any 24-hour period
- adults and children 12 years of age and older: take 2 softgels 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

\*\* 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:68016-147
<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

<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>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0K00R)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SORBITAN</b> (UNII: 6O92ICV9RU)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-147-16	2 in 1 CARTON	08/23/2017	
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	08/23/2017	

**Labeler** - Pharmacy Value Alliance, LLC (101668460)

### Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(68016-147) , analysis(68016-147)