

**COLD, FLU, AND SORE THROAT- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride capsule, liquid filled  
Meijer Distribution 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.*

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**Meijer Distribution, Inc. Cold, Flu & Sore Throat Drug Facts**

**Active ingredients (in each liquid gel)**

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 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 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day 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.
- 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
- 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:** In case of overdose, get medical help or contact a Poison Control Center right

away (1-800-222-1222). 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 10 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 at 20-25°C (68-77°F)

### **Inactive ingredients**

edible ink\*, FD&C red #40, FD&C yellow #6, gelatin, glycerin, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution \*may contain this ingredient

### **Questions or comments?**

1-800-719-9260

### **Package/Label Principal Display Panel**

Compare to Mucinex® Fast-Max® Cold, Flu & Sore Throat active ingredients

NON-DROWSY

MAXIMUM STRENGTH

cold, flu & sore throat

Acetaminophen | Pain Reliever | Fever Reducer

Dextromethorphan HBr | Cough Suppressant

Guaifenesin | Expectorant

Phenylephrine HCl | Nasal Decongestant

Fast Dissolving Liquid Gels

16 Liquid Gels

(Liquid Filled Capsules)

actual size

Controls Cough, Thins and Loosens Mucus

Relieves Nasal and Chest Congestion

Relieves Headache and Fever

For Ages 12+



## COLD, FLU, AND SORE THROAT

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

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-327
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
FD&C RED NO. 40 (UNII: WZB9127XOA)	

FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
GELATIN (UNII: 2G86QN327L)				
GLYCERIN (UNII: PDC6A3C0OX)				
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)				
POVIDONE (UNII: FZ989GH94E)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SORBITOL (UNII: 506T60A25R)				
SORBITAN (UNII: 6O92ICV9RU)				
Product Characteristics				
Color	ORANGE	Score	no score	
Shape	OVAL	Size	20mm	
Flavor		Imprint Code	13X	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-327-73	8 in 1 CARTON	04/30/2019	
1		2 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		04/30/2019	

**Labeler** - Meijer Distribution Inc (006959555)

**Registrant** - L. Perrigo Company (006013346)

Revised: 4/2019

Meijer Distribution Inc