

MUCINEX FAST-MAX SEVERE COLD- 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.

Mucinex FAST-MAX SEVERE COLD

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 common cold/flu symptoms:
- nasal congestion
- headache
- cough
- minor aches and pains
- sore throat
- temporarily reduces fever
- 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 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.

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 exceed 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 no. 6, gelatin, glycerin, lecithin (soy), mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol, titanium dioxide, water

Questions?

1-866-MUCINEX (1-866-682-4639)

PRINCIPAL DISPLAY PANEL - Carton Label

MUCINEX FAST-MAX SEVERE COLD 16 LIQUID GELS

NDC 51013-409-14

MAXIMUM STRENGTH*
Mucinex
FAST-MAX
SEVERE COLD

16 LIQUID GELS

Tamper evident: Do not use if carton is damaged or if printed seal on lid is broken or missing.

Fast Dissolving Liquid Gels!
MAXIMUM STRENGTH*
NDC 51013-409-14

Mucinex
FAST-MAX
SEVERE COLD

SEVERE COLD

Mucinex
FAST-MAX
SEVERE COLD

Also try the Max Strength, Multi-Symptom Mucinex® Fast-Max® Night Time products for night time cold & flu symptom relief

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

- ✓ Relieves Aches, Fever & Sore Throat
- ✓ Controls Cough
- ✓ Relieves Nasal & Chest Congestion
- ✓ Thins & Loosens Mucus

*Per 4-hour dose
Do not take more than a total of 12 liquid gels in a 24-hour period.
Take only as directed.
Keep carton for complete product information.

PARENTS:
Learn about your medicine choice
www.StopVaccineHoax.org

16 LIQUID GELS (Liquid Filled Capsules)
DAY TIME FOR AGES 12+

HEALTHY EFFICACY CLAIMS
www.mucinex.com
Dist. by: Reich Steiner
Paramaribo, NJ 07654-0224
Made in China
02017 NB
02017F 8288276

3 63824 59516 0

Drug Facts		Drug Facts (continued)
Active ingredients (in each liquid gel)	Purposes	<ul style="list-style-type: none"> tracheal irritation due to an enlarged prostate gland recurrent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema cough that occurs with too much phlegm (tracheal)
Acetaminophen 325 mg Pain reliever/fever reducer Dextromethorphan HBr 10 mg Cough suppressant Guaifenesin 200 mg Expectorant Phenylephrine HCl 5 mg Nasal decongestant		<p>When using this product do not use more than directed</p> <p>Stop use and ask a doctor if:</p> <ul style="list-style-type: none"> 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 fever, rash, or headache that lasts, these could be signs of a serious condition.
Uses		<p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>Keep out of reach of children.</p> <p>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.</p>
<ul style="list-style-type: none"> temporarily relieves these common cold and flu symptoms: <ul style="list-style-type: none"> runny nose cough minor aches and pains sore throat temporarily reduces fever helps loosen phlegm (tracheal) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive 		<p>Directions</p> <ul style="list-style-type: none"> 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
Warnings		Other information
<p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> 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 <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> skin redness hives rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>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.</p>		<ul style="list-style-type: none"> store between 20-25°C (68-77°F) avoid excessive heat
Do not use		Inactive ingredients
<ul style="list-style-type: none"> 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 nutritional 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. 		<p>FD&C yellow no. 6, gelatin, glycerin, lecithin (soy), mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol, titanium dioxide, water</p>
Ask a doctor before use if you have		Questions?
<ul style="list-style-type: none"> liver disease kidney disease thyroid disease heart disease high blood pressure 		<p>1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.</p>

MUCINEX FAST-MAX SEVERE COLD

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-409
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 YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

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 13-409-14	2 in 1 CARTON	05/23/2017	
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	05/23/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Humanwell PuraCap Pharmaceutical (Wuhan) Co., Ltd		421293287	manufacture(510 13-409) , analysis(510 13-409)

Revised: 11/2019

PuraCap Pharmaceutical LLC