MUCINEX FAST-MAX COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled RB Health (US) 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® Cold & Flu

Maximum Strength

Drug Facts

Active ingredients (in each liquid gel)	Purposes
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
 - stuffy nose
 - minor aches and pains
 - sore throat
 - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phelegm (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.

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 (precription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- if you are now taking a precription 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 precription 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
- persistant 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 fever, 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 over: 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)
- avoid excessive heat

Inactive ingredients

FD&C yellow no. 6, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

Questions?

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

You may also report side effects to this phone number.

Dist. by: RB Health (US) Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 16 Capsule Blister Pack Carton

Fast Dissolving Liquid Gels!

NDC 72854-126-16

MAXIMUM STRENGTH

MUCINEX® FAST-MAX®

COLD & FLU

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

HEADACHE SORE THROAT CHEST CONGESTION BODY PAIN FEVER COUGH NASAL CONGESTION SINUS CONGESTION SINUS PRESSURE

ALL IN ONE*

16 LIQUID GELS (Liquid Filled Capsules)

Actual Size

FOR AGES 12 +



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

COLD & FLU



Fast Dissolving Liquid Gels!

NDC 72854-126-161

MAXIMUM STRENGTH



COLD & FLU

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



Actual Size



FOR AGES 12+



3158959

LOT:

EXP.:

For Cold & Flu Multi-Symptom relief for both Day and Night, try our Maximum Strength

> Dist. by: RB Health (US) Parsippany, NJ 07054-0224 ©2021 RB Health

> > HEALTH + HYGIENE + HOME

www.mucinex.com



Drug Facts

Active ingredients (in each liquid gel)

Phenylephrine HCI 5 mg.

Purposes

.Nasal decongestant

minor aches and pains

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Drug Facts (continued)

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www.StopMedicineAbuse.org

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-126
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Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	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, UNSPECIFIED (UNII: 2G86QN327L)			
GLYCERIN (UNII: PDC6A3C0OX)			
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)			
ISOPROPYL ALCOHOL (UNII: ND2M416302)			
LIGHT MINERAL OIL (UNII: N6K5787QVP)			
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)			
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)			
WATER (UNII: 059QF0KO0R)			

Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	24mm	
Flavor		Imprint Code	AR01	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854- 126-16	2 in 1 CARTON	07/26/2021	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination		

1		Product		
2	NDC:72854- 126-08	1 in 1 CARTON	07/26/2021	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:72854- 126-10	1 in 1 CARTON	07/26/2021	
3		10 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	07/26/2021	

Labeler - RB Health (US) LLC (081049410)

Revised: 6/2023 RB Health (US) LLC