MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU- 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.

Maximum Strength Mucinex® Fast-Max® Cold and Flu

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
  - minor aches and pains
  - sore throat
  - sinus congestion and pressure
- 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 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 (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 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, lecithin (soy), mineral oil, polyethylene glycol, povidone, propylene glycol, purified water, shellac, sorbitol sorbitan solution, titanium dioxide

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

Made in China

PRINCIPAL DISPLAY PANEL - 16 Liquid Gel Blister Pack Carton

Fast Dissolving Liquid Gels!

NDC 63824-518-16

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

ALL IN
ONE*

NASAL CONGESTION

SINUS CONGESTION
SINUS PRESSURE

16
LIQUID GELS
(Liquid Filled Capsules)

FOR AGES 12 +

MAXIMUM STRENGTH
Mucinex
FAST-MAX
COLD & FLU

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

16 LIQUID GELS

Fast Dissolving Liquid Gels!

NDC 63824-518-16

MAXIMUM STRENGTH

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FAST-MAX®

COLD & FLU

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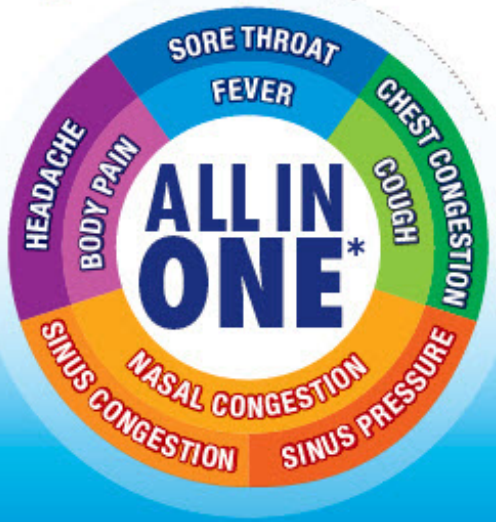

16 LIQUID GELS
(Liquid Filled Capsules)

FOR AGES 12+

*Helps to relieve these symptoms day or night

Maximum Strength per 4-hour dose

Do not take more than a total of 12 liquid gels in any 24-hour period.

Take only as directed.

Keep carton for full information.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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MAXIMUM STRENGTH
Mucinex
FAST-MAX
COLD & FLU

For Multi-Symptom relief for both Day and Night, try our **Maximum Strength Mucinex® FAST-MAX® Day/Night** packs

HEALTH • HYGIENE • HOME

www.mucinex.com
Patents: www.rb.com/patents

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Parsippany, NJ 07054-0224
Made in China

020519 8357062

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Drug Facts (continued)

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Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-518
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, unspecified (UNII: 2G86QN327L)	
glycerin (UNII: PDC6A3C0OX)	
lecithin, soybean (UNII: 1DI56QDM62)	
mineral oil (UNII: T5L8T28FGP)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
povidone, unspecified (UNII: FZ989GH94E)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
shellac (UNII: 46N107B71O)	
titanium dioxide (UNII: 15FIX9V2JP)	
SORBITAN (UNII: 6O92ICV9RU)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	ORANGE	**Score**	no score
Shape	OVAL	**Size**	24mm
Flavor		**Imprint Code**	PC26
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-518-16	2 in 1 CARTON	07/28/2018	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		

2	NDC:63824-518-08	1 in 1 CARTON	06/01/2020	
2		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	07/28/2018	

Labeler - RB Health (US) LLC (081049410)

Revised: 6/2020 RB Health (US) LLC