MUCINEX FAST-MAX COLD AND FLU- acetaminophen, guaifenesin, phenylephrine hydrochloride, and dextromethorphan hydrobromide tablet, film coated 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

Drug Facts

Active ingredients (in each caplet)	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 caplets 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 caplets in any 24-hour period
- adults and children 12 years of age and over: take 2 caplets every 4 hours
- children under 12 years of age: do not use

Other information

store between 20-25°C (68-77°F)

Inactive ingredients

corn starch, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions?

1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224

PRINCIPAL DISPLAY PANEL - 20 Caplet Blister Pack Carton

NDC 63824-514-01

MAXIMUM STRENGTH

Mucinex ®

FAST-MAX®

COLD & FLU

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

HEADACHE BODY PAIN

SORE THROAT

FEVER

CHEST CONGESTION COUGH

ALL IN

ONE*

NASAL CONGESTION
SINUS CONGESTION
SINUS PRESSURE
20 CAPLETS
FOR AGES 12+

NDC 63824-514-01

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COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer
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SORE THROAT

FEVER

BODY PAIN

SHUS CONGESTION SINUS PRESURE

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FOR AGES 12+

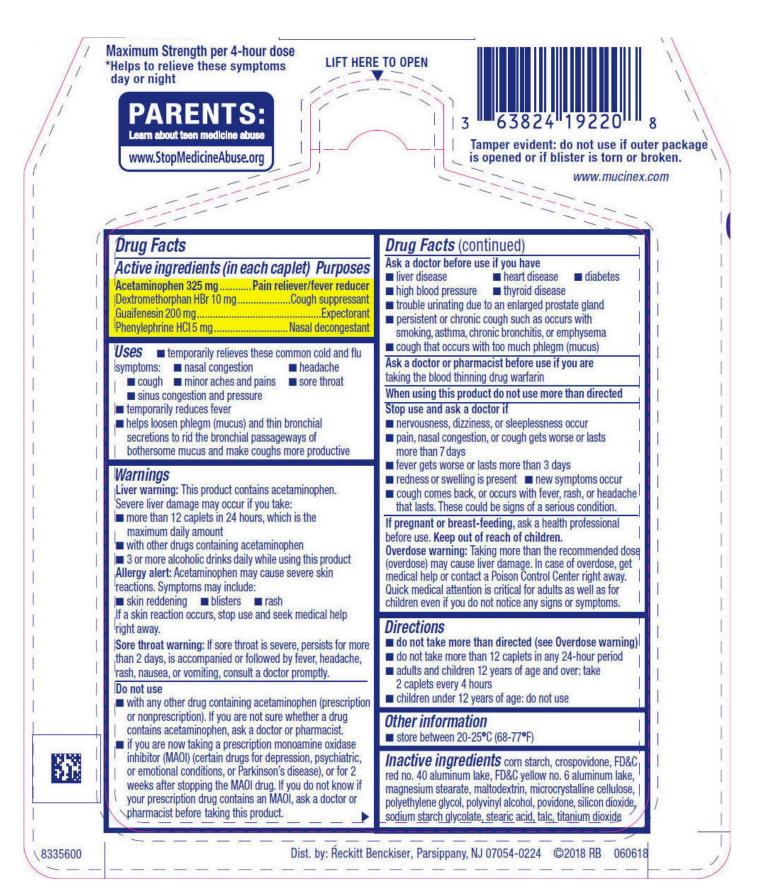
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Keep outer package for full information.



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MUCINEX FAST-MAX COLD AND FLU

acetaminophen, guaifenesin, phenylephrine hydrochloride, and dextromethorphan hydrobromide tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-514
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Acetaminophen (UNII: 36209ITL9D) (Acetaminophen - UNII:36209ITL9D)	Acetaminophen	325 mg	
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg	
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII: 1WS297W6MV)	Phenylephrine Hydrochloride	5 mg	
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg	

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C red no. 40 (UNII: WZB9127XOA)	
Aluminum oxide (UNII: LMI26O6933)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
magnesium stearate (UNII: 70097M6I30)	
maltodextrin (UNII: 7CVR7L4A2D)	
microcrystalline cellulose (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
sodium starch glycolate type a potato (UNII: 5856J3G2A2)	
stearic acid (UNII: 4ELV7Z65AP)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics				
Color	RED	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	DCH	
Contains				

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824- 514-01	2 in 1 CARTON	08/01/2018	
1		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	08/01/2018	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022 RB Health (US) LLC