MUCUS RELIEF SEVERE CONGESTION AND COUGH MAXIMUM STRENGTHdextromethorphan hbr, guaifenesin, phenylephrine hcl liquid Raritan Pharmaceuticals 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.

DRx Choice Maximum Strength Mucus Relief Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg
Phenylephrine HCl 10 mg

Purposes

Cough suppressant
Expectorant
Nasal Decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep
 - nasal congestion due to a cold

Warnings

Do not use

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

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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)

When using this product,

do not use more than directed.

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- symptoms do not get better within 7 days or occur with a fever
- cough comes back, or occurs with rash or persistent headache. 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.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- do not take more than 6 doses in a 24-hour period
- measure only with dosing cup provided.
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL=milliliter
- adults and children 12 years of age and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: Do not use

Other information

- each 20 mL contains: sodium 8 mg
- low sodium
- store at room temperature
- do not refrigerate
- dosing cup provided

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue No. 1, FD&C Red No. 40, flavor, potassium citrate, propylene glycol, propyl gallate, purified water, sodium benzoate, sorbitol, sucralose, xanthan gum

Questions or comments?

1-866-467-2748

Principal Display Panel

DRx CHOICE®

*Compare to the active ingredients Maximum Strength Mucinex[®] Fast-Max[™] Severe Congestion & Cough.

Maximum Strength

Mucus Relief

Severe Congestion and Cough

Dextromethorphan HBr 20 mg Cough Suppressant

Guaifenesin - EXPECTORANT

Phenylephrine HCI - Nasal Decongestant

- Controls Cough
- Relieves Nasal & Chest Congestion
- Thins & Loosens Mucus

FOR AGES 12 +

9 FL OZ (266 mL)

TAMPER EVIDENT: DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING.

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

#Maximum Strength per 4 hour dose.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick, NJ 08816

*This product is not manufactured or distributed by Reckitt Benckiser, distributor of Maximum Strength Mucinex® Fast-Max® Severe Congestion & Cough.















MUCUS RELIEF SEVERE CONGESTION AND COUGH MAXIMUM STRENGTH

dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-738
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

Inactive Ingredients		
Ingredient Name	Strength	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)		
EDETATE DISODIUM (UNII: 7FLD91C86K)		
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
POTASSIUM CITRATE (UNII: EE90ONI6FF)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
PROPYL GALLATE (UNII: 8D4SNN7V92)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		

SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163- 738-09	266 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/05/2019	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/05/2019	

Labeler - Raritan Pharmaceuticals Inc (127602287)

Revised: 9/2023 Raritan Pharmaceuticals Inc