MUCUS RELIEF COLD FLU AND SORE THROAT MAXIMUM STRENGTH- acetaminophen, dextromethorphan 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® Max Strength Mucus Relief Drug Facts

Active ingredients (in each 20 mL)

Acetaminophen 650 mg

Dextromethorphan HBr 20 mg

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purposes

Pain reliever/fever reducer

Cough suppressant

Expectorant

Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
    - nasal congestion
    - sinus congestion and pressure
    - cough due to minor throat and bronchial irritation
    - minor aches and pain
    - sore throat
    - headache
- temporarily reduces fever
- temporarily 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 6 doses 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.
- for children under 12 years of age
- 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
- 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)

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 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.

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 at 1-800-222-1222. 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 6 doses in any 24-hour period
- measure only with dosing cup provided. Do not use any other dosing device.
- 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
- 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 in Maximum Strength Mucinex® Fast-Max™ Cold, Flu & Sore Throat *

Maximum Strength

Mucus Relief

Cold, Flu & Sore Throat

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr • Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCl 10 mg • Nasal Decongestant

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

FOR AGES 12 +

9 FL OZ (266 mL)

*This product is not manufactured or distributed by Reckitt Benckiser, Distributor of Maximum Strength Mucinex® Fast-Max® Cold, Flu & Sore throat.

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

‡Maximum Strength per 4 hour dose.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick, NJ 08816

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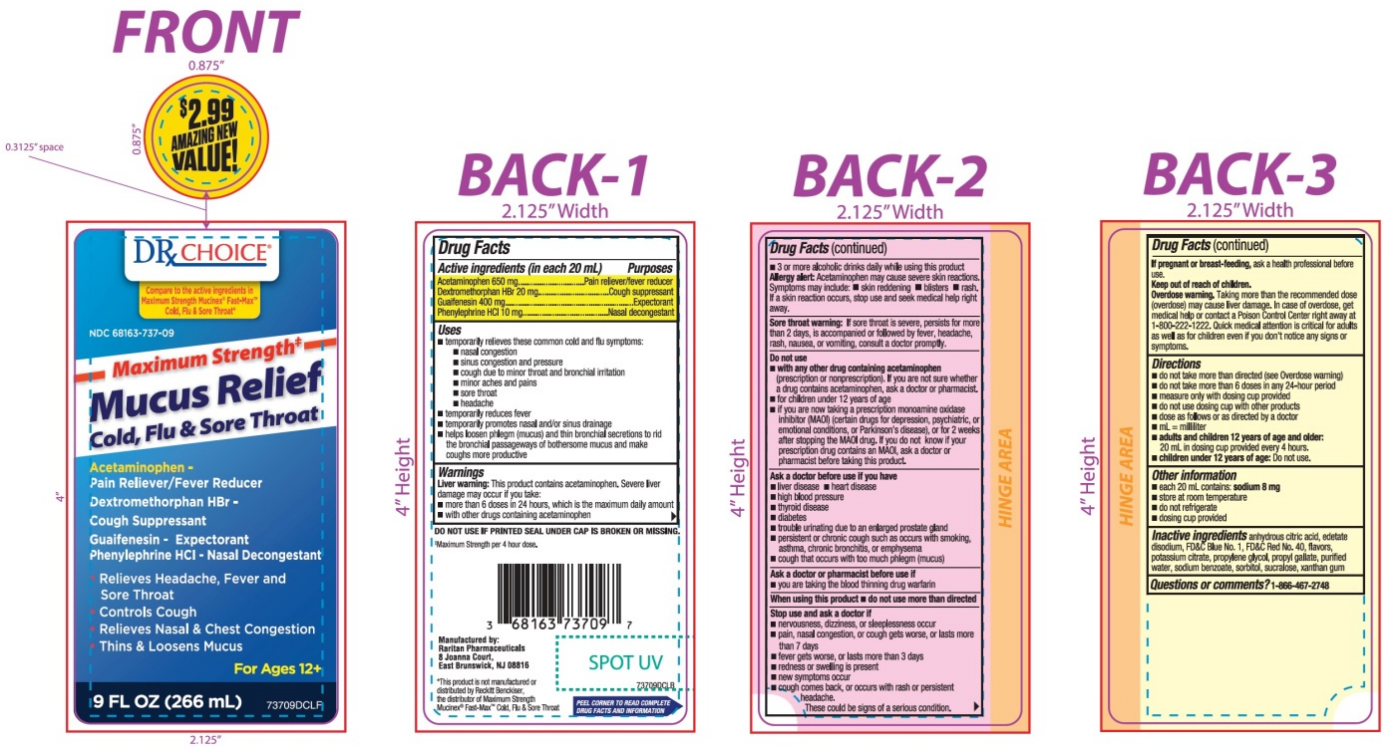
PEEL CORNER TO READ COMPELETE DRUG FACTS AND INFORMATION

Package Label



MUCUS RELIEF COLD FLU AND SORE THROAT MAXIMUM STRENGTH

acetaminophen, dextromethorphan hbr, guaifenesin, phenylephrine hcl liquid

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68163-737
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg in 20 mL
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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-737-09	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