MUCINEX NIGHT TIME SEVERE COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution
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 Night Time Severe Cold and Flu

Drug Facts

Active ingredients (in each 20 mL)	***Purposes***
Acetaminophen 650 mg	**Pain reliever/fever reducer**
Dextromethorphan HBr 20 mg	Cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant
Triprolidine HCl 2.5 mg	Antihistamine

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - sinus congestion and pressure
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- temporarily reduces fever
- controls cough to help you get to sleep

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4000 mg 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
- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, 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
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- use caution when driving a motor vehicle or operating machinery

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 4 doses in any 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
- adults and children 12 years of age and over: 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 16 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

ammonium glycyrrhizate, anhydrous citric acid, ascorbic acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), propylene glycol, sodium benzoate, sorbitol, sucralose, triacetin, triethyl citrate, water, xanthan gum

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 - 180 mL Bottle Label

NDC 72854-140-66

MAXIMUM STRENGTH

Mucinex®

SEVERE COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Phenylephrine HCl – Nasal Decongestant

Triprolidine HCl – Antihistamine

HEADACHE

SORE THROAT

ITCHY THROAT

BODY PAIN

FEVER

COUGH

ALL IN

ONE*

NASAL CONGESTION

SNEEZING

RUNNY NOSE

6 FL OZ (180 mL)

FOR AGES 12+

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Drug Facts (continued)

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PEEL HERE

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Questions?

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

Scan for FAQs and instructions on proper disposal of medicines

reckitt

Please visit our website www.mucinex.com

Patents: www.reckitt.com/patents

MUCINEX NIGHT TIME SEVERE COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72854-140
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
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 20 mL

TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	2.5 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIACETIN (UNII: XHX3C3X673)	
TRIETHYL CITRATE (UNII: 8Z96QXD6UM)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	blue	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-140-66	180 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package	05/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	05/01/2023	

Labeler - RB Health (US) LLC (081049410)

Revised: 6/2023 RB Health (US) LLC