

MUCINEX NIGHTSHIFT COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, 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® Nightshift
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
Triprolidine HCl 2.5 mg	Antihistamine

Uses

- temporarily relieves these common cold and flu symptoms:
 - cough
 - minor aches and pains
 - sore throat
 - headache
 - 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
- 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

- pain 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 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 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 63824-503-66

Mucinex®
NIGHTSHIFT

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Triprolidine HCl – Antihistamine

NIGHT TIME
RELIEF FOR A BETTER
MORNING

✓COUGH ✓FEVER ✓SORE THROAT
✓RUNNY NOSE ✓SNEEZING

6 FL OZ (180 mL)
FOR AGES 12+

NUC 63824-503-01

Mucinex® NIGHTSHIFT

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Triprolidine HCl – Antihistamine



✓ COUGH ✓ FEVER ✓ SORE THROAT
✓ RUNNY NOSE ✓ SNEEZING

3094783

6 FL OZ (180 mL) FOR AGES 12+

021519

**PEEL CORNER TO READ COMPLETE
DRUG FACTS AND INFORMATION**

Maximum Strength per 4-hour dose
Tamper evident: Do not use if neckband
on bottle cap is broken or missing.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org



Patents: www.rb.com/patents
Please visit our website
www.mucinex.com

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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022719

LOT:
EXP:
MADE IN:
3094785

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(in each 20 mL)

Purposes

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Dextromethorphan HBr 20 mg.....Cough suppressant
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Drug Facts (continued)

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.

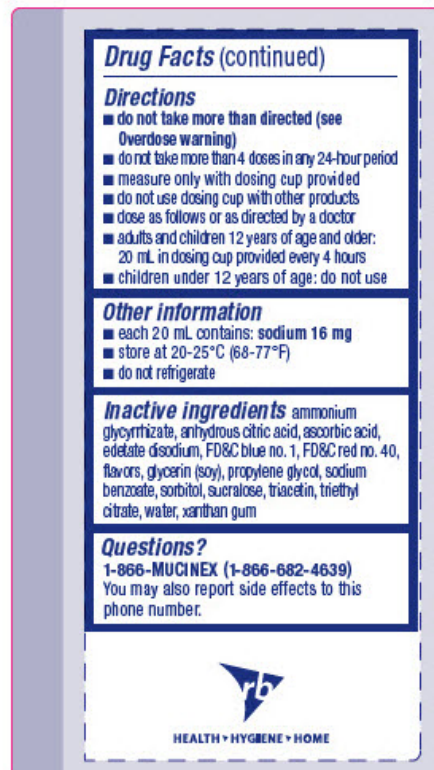
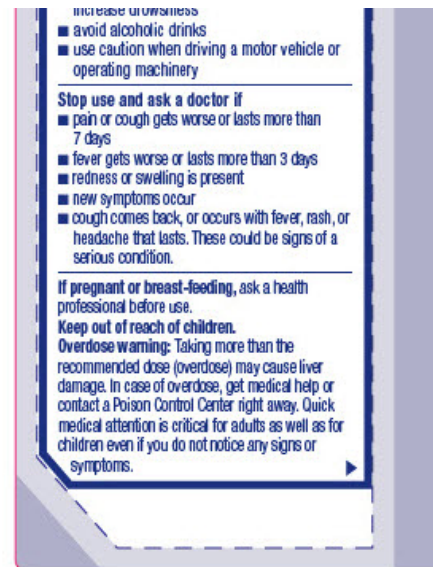
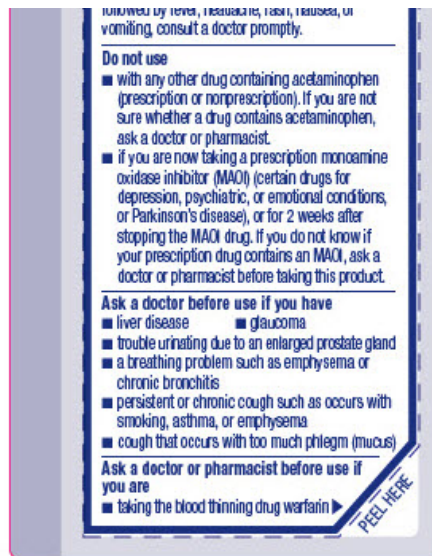
Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, pain in

Drug Facts (continued)

- taking sedatives or tranquilizers

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MUCINEX NIGHTSHIFT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-503
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
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:63824-503-66	180 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	06/15/2019	
2	NDC:63824-503-69	266 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)	06/15/2019	
3	NDC:63824-503-64	1 in 1 CARTON	06/15/2019	
3		118 mL in 1 BOTTLE; Type 9: Other Type of Part 3 Combination Product (e.g., Drug/Device/Biological Product)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/15/2019	

