

MUCINEX NIGHTSHIFT COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride tablet, 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® Nightshift Cold & Flu

Maximum Strength

Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10mg	Cough suppressant
Triprolidine HCl 1.25 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 4,000 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 8 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 at 20-25°C (68-77°F)

Inactive ingredients

croscarmellose sodium, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide

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 - 20 Caplet Blister Pack Carton

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

NDC 72854-233-20

MAXIMUM STRENGTH

Mucinex®
NIGHTSHIFT

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Triprolidine HCl – Antihistamine

NIGHTTIME

RELIEF FOR A BETTER

MORNING

✓COUGH ✓FEVER ✓SORE THOAT
✓RUNNY NOSE ✓SNEEZING

20 CAPLETS

FOR AGES 12+

ACTUAL SIZE

FAST
RELEASE

Tamper evident: Do not use if carton is damaged or if printed seal on blister is broken or missing.

MAXIMUM STRENGTH

Mucinex® COLD & FLU NIGHTSHIFT

FAST RELEASE. POWERFUL SYMPTOM RELIEF!

MAXIMUM STRENGTH

NDC 72854-233-20

Mucinex® NIGHTSHIFT

COLD & FLU

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



NIGHTTIME RELIEF FOR A BETTER MORNING

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



ACTUAL SIZE

FAST RELEASE

20 CAPLETS

FOR AGES 12+

LOT:
EXP.:
MADE IN:
3176291



Mucinex® NIGHTSHIFT

MAXIMUM STRENGTH

COLD & FLU

Maximum Strength per 4-hour dose
Do not take more than a total of 8 caplets in any 24-hour period.
Take only as directed.
Keep carton for full information.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

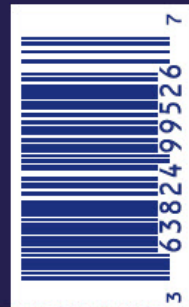


HEALTH • HYGIENE • HOME

www.mucinex.com
Packaging: www.rb.com/patients

Dist. by: RB Health (US)
Parlpspany, NJ 07054-0224
©2021 RB Health

3176291 011921





Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325 mg.....Pain reliever/fever reducer
 Dextromethorphan HBr 10 mg.....Cough suppressant
 Triprolidine HCl 1.25 mg.....Antihistamine

Purposes

Uses

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

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
 ■ more than 4,000 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

Drug Facts (continued)

- 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 8 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 at 20-25°C (68-77°F)

Inactive ingredients

croscarmellose sodium, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, polysorbate 80, povidone, titanium dioxide

Questions?

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

MUCINEX NIGHTSHIFT COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:72854-233

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	VW;LOGOcrescentmoon
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-233-20	2 in 1 CARTON	07/01/2021	
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	07/01/2021	

Labeler - RB Health (US) LLC (081049410)