

**MUCINEX FAST-MAX DM MAX AND MUCINEX NIGHTSHIFT COLD AND FLU-
acetaminophen, dextromethorphan hydrobromide, guaifenesin, and
triprolidine hydrochloride
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® DM Max and Mucinex® Nightshift Cold & Flu

Drug Facts

**Active ingredients
(in each 20 mL)
MUCINEX FAST-
MAX DM MAX**

Purposes

Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant

**Active ingredients (in
each 20 mL)
MUCINEX NIGHTSHIFT
COLD & FLU**

Purposes

Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Triprolidine HCl 2.5 mg	Antihistamine

Uses

MUCINEX FAST-MAX DM MAX

- 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

MUCINEX NIGHTSHIFT COLD & FLU

- 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 (Nightshift Cold & Flu only)

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 (Nightshift Cold & Flu only)

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 (Nightshift Cold & Flu only)

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. **(Nightshift Cold & Flu only)**
- 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 **(Nightshift Cold & Flu only)**
- glaucoma **(Nightshift Cold & Flu only)**
- trouble urinating due to an enlarged prostate gland **(Nightshift Cold & Flu only)**
- a breathing problem such as emphysema or chronic bronchitis **(Nightshift Cold & Flu only)**
- 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 **(Nightshift Cold & Flu only)**
- taking sedatives or tranquilizers **(Nightshift Cold & Flu only)**

When using this product

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

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days **(Nightshift Cold & Flu only)**
- fever gets worse or lasts more than 3 days **(Nightshift Cold & Flu only)**
- redness or swelling is present **(Nightshift Cold & Flu only)**
- new symptoms occur **(Nightshift Cold & Flu only)**
- cough comes back or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. **(Nightshift Cold & Flu only)**
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. **(Fast-Max DM Max only)**

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 right away.

Overdose warning (Nightshift Cold & Flu only)

Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

MUCINEX FAST-MAX DM MAX

- do not take more than 6 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

MUCINEX NIGHTSHIFT COLD & FLU

- **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 12 mg (Fast-Max DM Max only)** and **sodium 16 mg (Nightshift Cold & Flu only)**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients (MUCINEX FAST-MAX DM MAX)

anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate ¹, xanthan gum

1 may contain this ingredient

Inactive ingredients (MUCINEX NIGHTSHIFT COLD & FLU)

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 - Kit Carton

DAY & NIGHT
COUGH & COLD RELIEF

MAXIMUM STRENGTH
NDC 63824-118-66

Mucinex®
FAST-MAX®

DM MAX

Dextromethorphan HBr – Cough Suppressant

Guaifenesin - Expectorant

- Controls Cough
- Relieves Chest Congestion
- Thins & Loosens Mucus
- 4 Hour Dosing

Mucinex®

NIGHTSHIFT

COLD & FLU

Acetaminophen - Pain Reliever/Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Tripolidine HCl - Antihistamine

NIGHTTIME

RELIEF FOR A BETTER

MORNING

✓COUGH ✓FEVER ✓SORE THROAT

✓RUNNY NOSE ✓SNEEZING

FOR

AGES 12+

TWO - 6 FL OZ (180 mL) bottles

TOTAL - 12 FL OZ (360 mL)

FOR

AGES 12+

Drug Facts (continued)

Other information

- each 20 mL contains sodium 12 mg (Fast-Max DM Max only) and sodium 16 mg (Nightshift Cold & Flu only)
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

(MUCINEX FAST-MAX DM MAX)

- anhydrous citric acid, edetate disodium, FD&C red no. 40, flavors, glycerin (soy), propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate*, xanthan gum *may contain this ingredient

Inactive ingredients

(MUCINEX NIGHTSHIFT COLD & FLU)

- 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

Do not take Mucinex Fast-Max DM MAX and Mucinex Nightshift Cold & Flu at the same time. Always wait at least 4 hours before taking another dose of Mucinex liquid. TAKE ONLY AS DIRECTED.

PARENTS:

Learn about teen medicine abuse
www.StopMedicineAbuse.org

**DAY & NIGHT
COUGH & COLD RELIEF**

MAXIMUM STRENGTH

NDC 63824-118-66



DM MAX

Dextromethorphan HBr – Cough Suppressant
Guaifenesin – Expectorant

- ✓ Controls Cough
- ✓ Relieves Chest Congestion
- ✓ Thins & Loosens Mucus
- ✓ 4 Hour Dosing



COLD & FLU

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



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

FOR AGES 12+ TWO – 6 FL OZ (180 mL) bottles TOTAL – 12 FL OZ (360 mL) FOR AGES 12+

No coating

Dist. by: RB Health (US), Parsippany, NJ 07054-0224 Tamper evident: Do not use if neckband on bottle cap is broken or missing.

Drug Facts (continued)

Active ingredients (in each 20 mL) Purposes
MUCINEX NIGHTSHIFT COLD & FLU

- Acetaminophen 650 mg.....Pain reliever/fever reducer
- Dextromethorphan HBr 20 mg.....Cough suppressant
- Triprolidine HCl 2.5 mg.....Antihistamine

Drug Facts

Active ingredients (in each 20 mL) Purposes
MUCINEX FAST-MAX DM MAX

- Dextromethorphan HBr 20 mg.....Cough suppressant
- Guaifenesin 400 mg.....Expectorant

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin (Nightshift Cold & Flu only)
- taking sedatives or tranquilizers (Nightshift Cold & Flu only)
- When using this product, do not use more than directed
- excitability may occur, especially in children (Nightshift Cold & Flu only)
- marked drowsiness may occur (Nightshift Cold & Flu only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (Nightshift Cold & Flu only)
- avoid alcoholic drinks (Nightshift Cold & Flu only)
- use caution when driving a motor vehicle or operating machinery (Nightshift Cold & Flu only)

Stop use and ask a doctor if

- pain or cough gets worse or lasts more than 7 days (Nightshift Cold & Flu only)
- fever gets worse or lasts more than 3 days (Nightshift Cold & Flu only)
- redness or swelling is present (Nightshift Cold & Flu only)
- new symptoms occur (Nightshift Cold & Flu only)
- cough comes back or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (Nightshift Cold & Flu only)
- cough lasts more than 7 days, comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition. (Fast-Max DM MAX only)

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 right away.
Overdose warning (Nightshift Cold & Flu only): Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children seen if you do not notice any signs or symptoms.

Directions

- **MUCINEX FAST-MAX DM MAX**
- do not take more than 6 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
- **MUCINEX NIGHTSHIFT COLD & FLU**
- 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

Drug Facts (continued)

Uses **MUCINEX FAST-MAX DM MAX**

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

MUCINEX NIGHTSHIFT COLD & FLU

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

Warnings

Liver warning (Nightshift Cold & Flu only): 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 (Nightshift Cold & Flu only): Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- hives
- rash
- skin reaction occurs, stop use and seek medical help right away.

Some throat warning (Nightshift Cold & Flu only): 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. (Nightshift Cold & Flu only)
- 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 (Nightshift Cold & Flu only)
- glaucoma (Nightshift Cold & Flu only)
- trouble urinating due to an enlarged prostate gland (Nightshift Cold & Flu only)
- a breathing problem such as emphysema or chronic bronchitis (Nightshift Cold & Flu only)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)



HEALTH • HYGIENE • HOME



Questions?
 1-866-MUCINEX (1-866-682-4639)
 You may also report side effects
 to this phone number.
Maximum Strength per 4-hour dose

MUCINEX FAST-MAX DM MAX AND MUCINEX NIGHTSHIFT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and triprolidine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-118
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-118-66	1 in 1 CARTON	06/30/2022	

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	1 BOTTLE	180 mL
Part 2	1 BOTTLE	180 mL

Part 1 of 2

MUCINEX NIGHTSHIFT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride solution

Product Information

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
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)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	

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)		

Marketing Information

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

Part 2 of 2

MUCINEX FAST-MAX DM MAX

dextromethorphan hydrobromide and guaifenesin solution

Product Information

Item Code (Source)	NDC:63824-019
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

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	red	Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-019-66	180 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	07/18/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/20/2019	

Labeler - RB Health (US) LLC (081049410)

Revised: 6/2023

RB Health (US) LLC