MUCINEX FAST-MAX COLD AND FLU AND MUCINEX NIGHTSHIFT COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, 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 ®Cold & Flu and Mucinex® NightShift Cold & Flu

Drug Facts

Active ingredients (in each 20 mL) MUCINEX FAST-MAX COLD & FLU	***Purposes***
Acetaminophen 650 mg	**Pain reliever/fever reducer**
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10mg	Nasal decongestant

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 COLD & FLU

- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - stuffy nose
  - sinus congestion and pressure
- temporarily reduces fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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

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 **(Fast-Max Cold & Flu only)**
- diabetes **(Fast-Max Cold & Flu only)**

- high blood pressure **(Fast-Max Cold & Flu only)**
- thyroid disease **(Fast-Max Cold & Flu only)**
- glaucoma **(Nightshift Cold & Flu only)**
- trouble urinating due to an enlarged prostate gland
- 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
- 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
- nervousness, dizziness, or sleeplessness occur **(Fast-Max Cold & Flu only)**
- pain, nasal congestion, or cough gets worse or lasts more than 7 days **(Fast-Max Cold & Flu only)**
- pain or cough gets worse or lasts more than 7 days **(Nightshift Cold & Flu only)**
- 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

MUCINEX FAST-MAX COLD & FLU

- **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 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 Cold & Flu 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 COLD & FLU)

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

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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

NDC 63824-137-66

MAXIMUM STRENGTH

Mucinex®
FAST-MAX ®

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer
Dextromethorphan HBr – Cough Suppressant
Guaifenesin – Expectorant • Phenylephrine HCl – Nasal Decongestant

SORE THROAT
FEVER
HEADACHE
BODY PAIN
ALL IN
ONE*
CHEST CONGESTION
COUGH
NASAL CONGESTION
SINUS CONGESTION
SINUS PRESSURE

FOR AGES 12+

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

FOR AGES 12+

THREE – 6 FL OZ (180 mL) bottles TOTAL – 18 FL OZ (540 mL)

NDC 63824-137-66

MAXIMUM STRENGTH

Mucinex FAST-MAX

COLD & FLU

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THREE – 6 FL OZ (180 mL) bottles TOTAL – 18 FL OZ (540 mL)

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

FOR AGES 12+

No coating

Drug Facts (continued)

Ask a doctor or pharmacist before use if you are
- taking the blood thinning drug warfarin
- 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 drink (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
- nervousness, dizziness, or sleeplessness occur (Fast-Max Cold & Flu only)
- pain, nasal congestion, or cough gets worse or lasts more than 7 days (Fast-Max Cold & Flu only)
- pain or cough gets worse or lasts more than 7 days (Nightshift Cold & Flu only)
- 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

MUCINEX FAST-MAX COLD & FLU
- 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 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 Cold & Flu 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 COLD & FLU)
anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavors, glycerin (soy), 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

Questions? 1-800-MUCINEX (1-800-682-4639)
You may also report side effects to this phone number.

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

Drug Facts

Active ingredients (in each 20 mL) Purposes
MUCINEX FAST-MAX COLD & FLU

Acetaminophen 650 mg	Pain reliever/fever reducer
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

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

Uses MUCINEX FAST-MAX COLD & FLU
- temporarily relieves these common cold and flu symptoms:
  - cough
  - nasal congestion
  - minor aches and pains
  - sore throat
  - headache
  - stuffy nose
  - sinus congestion and pressure
- temporarily reduce fever
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive

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: 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
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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 (Fast-Max Cold & Flu only)
- diabetes (Fast-Max Cold & Flu only)
- high blood pressure (Fast-Max Cold & Flu only)
- thyroid disease (Fast-Max Cold & Flu only)
- glaucoma (Nightshift Cold & Flu only)
- trouble urinating due to an enlarged prostate gland
- 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)

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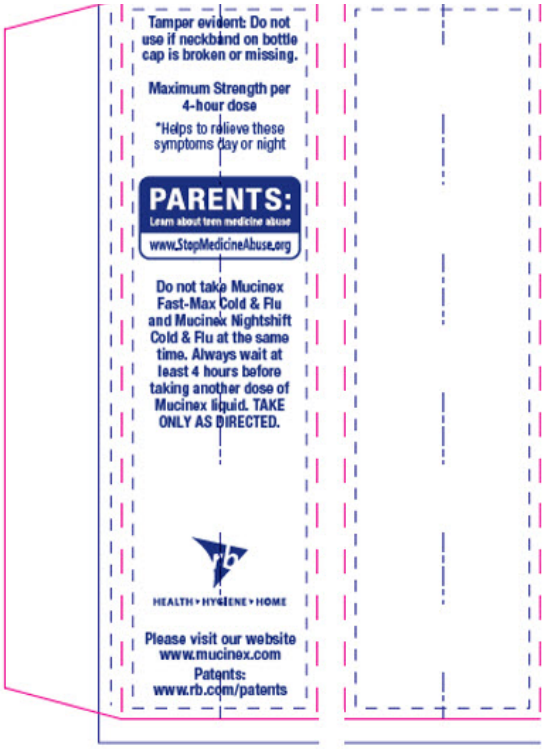

MUCINEX FAST-MAX COLD AND FLU AND MUCINEX NIGHTSHIFT COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-137

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63824-137-66	1 in 1 CARTON	08/05/2019	09/01/2024

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	180 mL
Part 2	2 BOTTLE	360 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
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)		

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

MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride solution

Product Information

Item Code (Source)	NDC:63824-548
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)	
PROPYL GALLATE (UNII: 8D4SNN7V92)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
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	blue	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-548-66	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	07/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/05/2019	09/01/2024

Labeler - RB Health (US) LLC (081049410)

Revised: 8/2023 RB Health (US) LLC