

MUCINEX FAST-MAX COLD AND FLU AND MUCINEX NIGHTTIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, and triprolidine hydrochloride
RB Health (US) LLC

Maximum Strength Mucinex® Fast-Max® Cold & Flu and Mucinex® NightShift Severe Cold & Flu

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 SEVERE COLD & FLU		
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

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 SEVERE COLD & FLU

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

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

When using this product

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

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

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 SEVERE 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 Severe Cold & Flu only)**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients (MUCINEX FAST-MAX COLD & FLU)

ammonium glycyrrhizate, anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate†, xanthan gum
†may contain this ingredient

Inactive ingredients (MUCINEX NIGHTSHIFT SEVERE 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 72854-154-26

DAY & NIGHT COLD & FLU PACK

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+

TWO – 6 FL OZ (180 mL) bottles

MAXIMUM STRENGTH

Mucinex®

NIGHTTIME

COLD & FLU

Acetaminophen – Pain Reliever/Fever Reducer

Dextromethorphan HBr – Cough Suppressant

Phenylephrine HCl – Nasal Decongestant • Triprolidine HCl – Antihistamine

SORE THROAT

FEVER

HEADACHE

BODY PAIN

ALL IN

ONE*

ITCHY THROAT

COUGH

NASAL CONGESTION

SNEEZING

RUNNY NOSE

TOTAL – 12 FL OZ (360 mL)

FOR

AGES 12+

Mucinex®

POWERFUL MULTI-SYMPTOM RELIEF

ALL IN ONE COLD & FLU RELIEF » DAY & NIGHT



NDC 72854-154-26

NIGHTTIME SEVERE COLD & FLU
(cont'd)

Drug Facts (continued)

- 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 (syr), propylene glycol, sodium benzoate, sorbitol, sucralose, triacetin, triethyl citrate, water, xanthan gum

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

POWERFUL RELIEF
FOR YOUR NIGHT
+
POWERFUL RELIEF
FOR YOUR DAY



Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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3285341 100424

RELIEF FOR YOUR DAY

RELIEF FOR YOUR NIGHT

AGES
12+

TWO - 6 FL OZ (180 mL) bottles

TOTAL - 12 FL OZ (360 mL)

AGES
12+

NIGHTTIME SEVERE COLD & FLU		COLD & FLU	
Drug Facts		Drug Facts	
Active ingredients (in each 20 mL)		Active ingredients (in each 20 mL)	
Acetaminophen 650 mgPain reliever/fever reducer Dextromethorphan HBr 20 mgCough suppressant Phenylephrine HCl 10 mgNasal decongestant Triprolidine HCl 2.5 mgAntihistamine		Acetaminophen 650 mgPain reliever/fever reducer Dextromethorphan HBr 20 mgCough suppressant Guaifenesin 400 mgExpectorant Phenylephrine HCl 10 mgNasal decongestant	
Purposes		Purposes	
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		Uses ■ 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	
Warnings		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.		Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 6 doses 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		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.		■ 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		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)		■ liver disease ■ heart disease ■ diabetes ■ high blood pressure ■ thyroid disease ■ trouble urinating due to an enlarged prostate gland ■ 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		Ask a doctor or pharmacist before use if you are	
■ taking the blood thinning drug warfarin ■ taking sedatives or tranquilizers		■ taking the blood thinning drug warfarin	
When using this product		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		■ do not use more than directed ■ 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.	
Stop use and ask a doctor if		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		■ 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	
Keep out of reach of children.		Keep out of reach of children.	

Drug Facts (continued)

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 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

Other information

- each 20 mL contains: **sodium 12 mg**
- store at 20-25°C (68-77°F)
- do not refrigerate

Inactive ingredients

ammonium glycyrrhizate, anhydrous citric acid, edetate disodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate, xanthan gum
 *may contain this ingredient

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

***FAST-MAX COLD & FLU**
 helps to relieve these symptoms day or night; **FAST-MAX NIGHTTIME SEVERE COLD & FLU** helps to relieve these symptoms at night

Do not take Mucinex Fast-Max Cold & Flu and Mucinex Fast-Max Nighttime Severe Cold & Flu at the same time. Always wait at least 4 hours before taking another dose of Mucinex liquid.

TAKE ONLY AS DIRECTED.

Maximum Strength per 4-hour dose



MUCINEX FAST-MAX COLD AND FLU AND MUCINEX NIGHTTIME COLD AND FLU

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72854-154
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-154-26	1 in 1 CARTON	06/01/2025	

Quantity of Parts

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

Part 2	1 BOTTLE	180 mL
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Part 1 of 2

MUCINEX NIGHTSHIFT SEVERE COLD AND FLU

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

Product Information

Item Code (Source)	NDC:63824-504
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
GLYCERIN (UNII: PDC6A3C0OX)	
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	
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Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-504-66	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 Drug	M012	06/01/2020	

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
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

GLYCERIN (UNII: PDC6A3C0OX)	
PROPYL GALLATE (UNII: 8D45NN7V92)	
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 Drug	M012	07/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	06/01/2025	

Labeler - RB Health (US) LLC (081049410)

Establishment

Name	Address	ID/FEI	Business Operations
Reckitt Benckiser LLC		111829557	label(72854-154)

Establishment

Name	Address	ID/FEI	Business Operations
Reckitt Benckiser (UK) Ltd.		227363660	manufacture(72854-154)

