MUCINEX FAST-MAX DAY COLD AND FLU AND MUCINEX NIGHTSHIFT NIGHT SEVERE COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride RB Health (US) LLC

#### MUCINEX® FAST-MAX® Daytime Cold & Flu & Nighttime Cold & Flu Caplets Drug Facts

#### Daytime Cold & Flu

Acetaminophen 325 mg Dextromethorphan HBr 10 mg

#### Mucinex Nighttime Cold & Flu

Acetaminophen 325 mg Dextromethorphan HBr 10 mg Triprolidine HCI 1.25 mg

Active	ingredients	(in	each
caplet)			

Purposes

#### Mucinex Fast-Max Day Cold & Flu

Acetaminophen 325 mg

Pain reliever/fever reducer

Dextromethorphan HBr 10 mg Cough suppressant

Active ingredients (in each

caplet)

**Purposes** 

**Mucinex Nightshift Night** Severe Cold & Flu

Acetaminophen 325 mg

Pain reliever/fever reducer

Dextromethorphan HBr 10 mg Cough suppressant Triprolidine HCl 1.25 mg

**Antihistamine** 

#### Uses

#### Mucinex Fast-Max Day 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 Night 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 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
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma (Nightshift Night Severe Cold & Flu only)
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis (Nightshift Night 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 Night Severe Cold & Flu only)

#### When using this product

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

- do not take more than directed (see Overdose warning)
- do not take more than 12 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

#### Mucinex Nightshift Night Severe Cold & Flu

- 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 Mucinex Fast-Max Day Cold & Flu

croscarmellose sodium, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, talc, titanium dioxide

#### Inactive ingredients Mucinex Nightshift Night Severe Cold & Flu

croscarmellose sodium, crospovidone, ferric oxide, hydroxypropyl cellulose, mica, microcrystalline cellulose, polyvinyl alcohol, polyvinyl alcohol polyethylene glycol copolymer, povidone, silicon dioxide, stearic acid, talc, 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 - Kit Carton

NDC 72854-169



**NEW FORMULAS** 

FAST-MAX

\*Fast-Max® Daytime Cold & Flu helps to relieve these symptoms day or night; Fast-Max® Nighttime Cold & Flu helps to relieve these symptoms at night

DAYOTIME COLD & FLU

Maximum Strength per 4-hour dose

reckitt @

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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Patents: www.reckitt.com/ patents

Take only as directed.

Keep carton for full information

COLD & FLU

MAXIMUM STRENGTH

MAXIMUM STRENGTH

NDC 72854-169-40

**等AST** MAX®

DAY®TIME COLD & FLU

Acetaminophen » Pain Reliever/Fever Reducer Dextromethorphan HBr » Cough Suppressant

NIGHT CTIME COLD & FLU

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

**AGES 12+** AGES 12+ SORETHROAT COUGH BODY ACHES FEVER HEADACHE MINOR PAINS

**TOTAL 40 CAPLETS** 

NIGHTTIME COLD & FLU (cont'd)

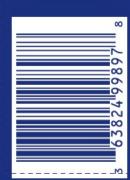
DAYTIME COLD & FLU (cont'd)

16 CAPLETS

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







Do not take the Mucinex® Fast-Max® Daytime Cold & Flu and Mucinex® Fast-Max® Nighttime Cold & Flu caplets at the same time. Always wait at least 4 hours before taking another dose of Mucinex® caplets. Keep carton for complete product information. Do not take more than directed (see Overdose warning). DAYTIME COLD & FLU NIGHTTIME COLD & FLU

Drug Facts

Drug Facts

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alinge DAYTIME COLD & FLU (cont'd) NIGHTTIME COLD & FLU (cont'd) rua Facts (continued) Drug Facts (continued) more than 12 caplets in any 24-hour Idren 12 years of age and over: warning)
do not take more than 8 caplets in any 24-hour period adults and children 12 years of age and over: take 2 capiets every 4 hours children under 12 years of age: do not use Other information

store at 20-25°C (68-77°F) tions? 1-866-MUCINEX (1-866-682-463

## MUCINEX FAST-MAX DAY COLD AND FLU AND MUCINEX NIGHTSHIFT NIGHT SEVERE COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride kit

#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72854-169

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72854-169-10	1 in 1 CARTON	07/01/2025		
1		1 in 1 KIT			
2	NDC:72854-169-20	2 in 1 CARTON	07/01/2025		
2		1 in 1 KIT			
3	NDC:72854-169-40	4 in 1 CARTON	07/01/2025		
3		1 in 1 KIT			

Quantity of Parts			
Part #	Package Quantity	Total Product Quantity	
Part 1	1 BLISTER PACK	6	
Part 2	1 BLISTER PACK	4	

#### Part 1 of 2

#### **MUCINEX FAST-MAX COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide tablet

#### **Product Information**

Item Code (Source) NDC:72854-161

**Route of Administration** ORAL

# Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN - UNII:7355X3ROTS) DEXTROMETHORPHAN HYDROBROMIDE 10 mg

Inactive Ingredients		
Ingredient Name	Strength	
CROSCARMELLOSE SODIUM (UNII: M280L1HH48)		
CROSPOVIDONE (UNII: 2S7830E561)		

FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	Score	no score
Shape	OVAL	Size	8mm
Flavor		Imprint Code	Chevron
Contains			

Pa	ckaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1		6 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 Drug	M012	04/01/2025	

#### Part 2 of 2

#### MUCINEX NIGHTSHIFT COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, and triprolidine hydrochloride tablet, coated

<b>Product Information</b>	
Item Code (Source)	NDC:72854-163
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	325 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (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)		
CROSPOVIDONE (UNII: 2S7830E561)		
FERRIC OXIDE RED (UNII: 1K09F3G675)		
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)		
MICA (UNII: V8A1AW0880)		
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
POLYVINYL ALCOHOL GRAFT POLYETHYLENE GLYCOL COPOLYMER (3:1; 45000 MW) (UNII: 23ZQ42JZZH)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)		

Product Characteristics				
Color	white	Score	no score	
Shape	OVAL	Size	19mm	
Flavor		Imprint Code	VW;LOGOcres centmoon	
Contains				

Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1		4 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 Drug	M012	04/01/2025						

Marketing Information								
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date					
OTC Monograph Drug	M012	07/01/2025						

### Labeler - RB Health (US) LLC (081049410)

Revised: 4/2025 RB Health (US) LLC