MUCINEX FAST-MAX DAY COLD AND FLU AND MUCINEX NIGHTSHIFT NIGHT SEVERE COLD AND FLU MAXIMUM STRENGTH- 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 ® Day Cold & Flu and Mucinex Nightshift Night Severe Cold & Flu

Maximum Strength

Drug Facts

Active ingredients (in each caplet) Mucinex Fast-Max Day Cold & Flu	e Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant
Active ingredients (in each caplet) Mucinex Nightshift Night Severe Cold & Flu	Purposes
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg	Cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant
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

FAST RELEASE, POWERFUL SYMPTOM RELIEF!

NDC 72854-241-20

MAXIMUM STRENGTH

Mucinex ®

FAST-MAX ® NIGHTSHIFT

DAY

COLD & FLU

Acetaminophen - Pain Reliever/

Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCI - Nasal Decongestant

HEADACHE

SORE THROAT

CHEST CONGESTION

BODY PAIN

FEVER

COUGH

ALL IN

ONE*

NASAL CONGESTION

SINUS CONGESTION

SINUS PRESSURE

ACTUAL SIZE

FOR AGES 12+

12 CAPLETS

FAST

RELEASE

NIGHT

SEVERE COLD & FLU

Acetaminophen - Pain Reliever/

Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Phenylephrine HCI - Nasal Decongestant

Triprolidine HCl - Antihistamine

HEADACHE

SORE THROAT

ITCHY THROAT

BODY PAIN

FEVER

COUGH

ALL IN

ONE*

NASAL CONGESTION

SNEEZING RUNNY NOSE

ACTUAL SIZE

FOR AGES 12+

8 CAPLETS

TOTAL 20 CAPLETS



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

Drug Facts

AKE ONLY AS DIRECTED.

Active ingredients (in each caplet)

Purposes

	Mucinov Fact May Day Cold & Flu
Н	Mucinex Fast-Max Day Cold & Flu
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밁	Phenylephrine HCl 5 mgNasal decongestant
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	Dextromethorphan HBr 10 mg
	Phenylephrine HCl 5 mgNasal decongestant
Ě	Triprolidine HCl 1.25 mgAntihistamine
	Uses
ě	Mucinex Fast-Max Day Cold & Flu
ã	temporarily relieves these common cold and flu symptoms:
S	■ cough ■ nasal congestion ■ minor aches and pains ■ sore throat ■ stuffy nose ■ sinus congestion and pressure
a	■ headache ■ stuffy nose ■ sinus congestion and pressure
B	 temporarily reduces fever helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial
	passageways of bothersome mucus and make coughs more productive
0	Mucinex Nightshift Night Severe Cold & Flu
8	temporarily relieves these common cold and flu symptoms:
P	■ cough
Ξ	■ headache ■ sneezing ■ sinus congestion and pressure ■ runny nose
5	■ itching of the nose or throat
B	■ itchy, watery eyes due to hay fever ■ temporarily reduces fever
3	controls cough to help you get to sleep
2	The grant was provided the control of the control o
3	Warnings
A	Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:
3	more than 4,000 mg in 24 hours, which is the maximum daily amount
2	with other drugs containing acetaminophen
FO	3 or more alcoholic drinks daily while using this product
8	Allergy alert: Acetaminophen may cause severe skin reactions.
A	Symptoms may include: ■ skin reddening ■ blisters ■ rash
PEEL CORNER JO BEAD COMPLETE DRUG FACTS AND JUFORMATION	If a skin reaction occurs, stop use and seek medical help right away.
~	-

Reseal Area

Drug Facts (continued)

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.

diabetes

Ask a doctor before use if you have

- Iiver disease
- heart disease
- 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 & Flu only)
 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)



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

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

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:72854-241

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:72854-241-10	1 in 1 CARTON	07/01/2021		
1		1 in 1 KIT			
2	NDC:72854-241-20	2 in 1 CARTON	07/01/2021		

	2		1 in 1 KIT		
l	3	NDC:72854-241-40	4 in 1 CARTON	07/01/2021	
	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

MAXIMUM STRENGTH MUCINEX FAST-MAX COLD AND FLU

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, film coated

Product Information		
Item Code (Source)	NDC:63824-575	
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
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
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	20mm
Flavor		Imprint Code	MSC;VVV
Contains			

Pac	ckaging			
#	Item 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 final	part341	07/01/2021		

Part 2 of 2

MUCINEX NIGHTSHIFT SEVERE COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, phenylephrine hydrochloride, and triprolidine hydrochloride tablet, coated

Product Information		
Item Code (Source)	NDC:72854-234	
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	
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg	
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg	

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

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	yellow	Score	no score
Shape	OVAL	Size	19mm
Flavor		Imprint Code	WW;LOGOcres centmoonplus
Contains			

Pa	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1		4 in 1 BLISTER PACK; Type 0: Not a Combination Product			

Marketing In			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2021	

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)

Revised: 6/2023 RB Health (US) LLC