MUCINEX FAST-MAX DAY TIME COLD AND FLU AND NIGHT TIME COLD AND FLU- acetaminophen, dextromethrophan hydrobromide, guaifenesin, phenylephrine hydrochloride, and diphenhydramine hydrochloride
RB Health (US) LLC

Mucinex® Fast-Max ®
Day Time Cold & Flu and Night Time Cold & Flu

Drug Facts

Active ingredients (in each caplet) Mucinex FAST-MAX DAY TIME COLD & FLU	***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 FAST-MAX NIGHT TIME COLD & FLU	***Purposes***
Acetaminophen 325 mg	**Pain reliever/fever reducer**
Diphenhydramine HCl 12.5 mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves these common cold and flu symptoms:
  - cough
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - sinus congestion and pressure
  - runny nose ***(NIGHT TIME only)***
  - sneezing ***(NIGHT TIME only)***
  - itching of the nose or throat ***(NIGHT TIME only)***
  - itchy, watery eyes due to hay fever ***(NIGHT TIME only)***
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ***(DAY TIME only)***
- controls cough to help you get to sleep

- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:
- more than 12 caplets 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.
- with any other product containing diphenhydramine, even one used on the skin ***(NIGHT TIME 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
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma ***(NIGHT TIME only)***
- a breathing problem such as emphysema or chronic bronchitis ***(NIGHT TIME 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 ***(NIGHT TIME only)***

When using this product
- **do not use more than directed**
- excitability may occur, especially in children ***(NIGHT TIME only)***
- marked drowsiness may occur ***(NIGHT TIME only)***
- alcohol, sedatives, and tranquilizers may increase drowsiness ***(NIGHT TIME only)***
- avoid alcoholic drinks ***(NIGHT TIME only)***
- be careful when driving a motor vehicle or operating machinery ***(NIGHT TIME 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
- **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

Other information
- store between 20-25°C (68-77°F)

Inactive ingredients (Mucinex FAST-MAX DAY TIME COLD & FLU)

corn starch, crospovidone, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium starch glycolate, stearic acid, talc, titanium dioxide

Inactive ingredients (Mucinex FAST-MAX NIGHT TIME COLD & FLU)

corn starch, croscarmellose sodium, crospovidone, FD&C blue no. 1 aluminum lake, FD&C blue no. 2 aluminum lake, ferric oxide yellow, magnesium stearate, methacrylic acid-ethyl acrylate copolymer (1:1) type A, mica, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, silicon dioxide, sodium bicarbonate, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL - Kit Carton

MAXIMUM STRENGTH

NDC 63824-516-01

Mucinex®
FAST-MAX ®

DAY
TIME
COLD & FLU

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

HEADACHE
BODY PAIN
SORE THROAT
FEVER
CHEST CONGESTION
COUGH
NASAL CONGESTION
SINUS CONGESTION SINUS PRESSURE

ALL IN
ONE*

20 CAPLETS
FOR AGES 12+

NIGHT
TIME
COLD & FLU

Acetaminophen - Pain Reliever/Fever Reducer
Diphenhydramine HCl - Antihistamine/
Cough Suppressant
Phenylephrine HCl - Nasal Decongestant

HEADACHE
BODY PAIN
SORE THROAT
FEVER
ITCHY THROAT

COUGH
NASAL CONGESTION
SNEEZING RUNNY NOSE

ALL IN
ONE*

10 CAPLETS
FOR AGES 12+

TOTAL 30 CAPLETS

Drug Facts

Active ingredients (in each caplet)	Purposes
Mucinex FAST-MAX DAY TIME COLD & FLU	
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)	Purposes
Mucinex FAST-MAX	

Drug Facts (continued)

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive ***(DAY TIME only)***
- controls cough to help you get to sleep
- temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 12 caplets in 24 hours, which is the maximum daily

Drug Facts (continued)

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.
- with any other product containing diphenhydramine, even one used on the skin ***(NIGHT TIME only)***
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or

Drug Facts (continued)

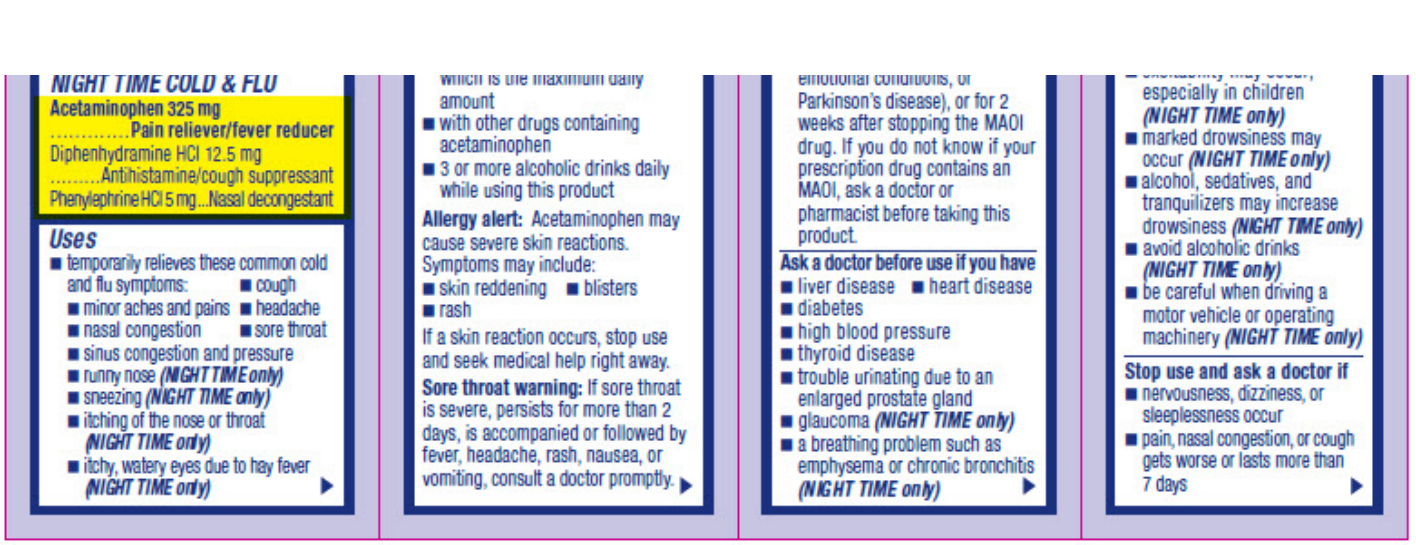
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if you are

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers ***(NIGHT TIME only)***

When using this product

- **do not use more than directed**
- excitability may occur



MUCINEX FAST-MAX DAY TIME COLD AND FLU AND NIGHT TIME COLD AND FLU

acetaminophen, dextromethrophan hydrobromide, guaifenesin, phenylephrine hydrochloride, and diphenhydramine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-516

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:63824-516-01	1 in 1 PACKAGE, COMBINATION	12/10/2018	02/16/2025

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	2 BLISTER PACK	20
Part 2	1 BLISTER PACK	10

Part 1 of 2

MUCINEX FAST-MAX COLD AND FLU

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

Product Information	
Item Code (Source)	NDC:63824-514
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	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**
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	red	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	DCH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-514-01	2 in 1 CARTON		
1		10 in 1 BLISTER PACK; 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	08/01/2018	

Part 2 of 2

MUCINEX FAST-MAX NIGHT TIME COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, film coated

Product Information	
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPOVIDONE (UNII: 2S7830E561)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
METHACRYLIC ACID AND ETHYL ACRYLATE COPOLYMER (UNII: NX76LV5T8J)	
MICA (UNII: V8A1AW0880)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	blue	**Score**	no score
Shape	OVAL	**Size**	19mm
Flavor		**Imprint Code**	MVA
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		10 in 1 BLISTER PACK; 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	08/01/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	12/01/2018	02/16/2025

Labeler - RB Health (US) LLC (081049410)