

MAXIMUM STRENGTH MUCINEX FAST-MAX DAY TIME COLD AND FLU AND NIGHT TIME COLD AND FLU- acetaminophen, dextromethorphan hydrobromide, diphenhydramine hydrochloride, guaifenesin, and phenylephrine 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.

Maximum Strength Mucinex® Fast-Max® Day Time Cold & Flu and Night Time Cold & Flu
Drug Facts

Active ingredients (in each caplet)	Purposes
Mucinex FAST-MAX DAY TIME COLD & FLU	
Acetaminophen 325 mg	Pain reliever/fever reducer
Dextromethorphan HBr 10mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

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

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 FAST-MAX NIGHT TIME COLD & FLU)

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

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - Kit Carton

MAXIMUM STRENGTH

NDC 63824-511-30

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
ALL IN
ONE*
NASAL CONGESTION
SINUS CONGESTION
SINUS PRESSURE

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
ALL IN
ONE*
NASAL CONGESTION
SNEEZING
RUNNY NOSE

10 CAPLETS
FOR AGES 12+

TOTAL 30 CAPLETS

MAXIMUM STRENGTH NDC 63824-511-30

Mucinex[®]

FAST-MAX[®]



COLD & FLU

Acetaminophen - Pain Reliever/Fever Reducer
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20 CAPLETS



FOR AGES 12+



COLD & FLU

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Cough Suppressant
Phenylephrine HCl - Nasal Decongestant



10 CAPLETS



FOR AGES 12+

TOTAL 30 CAPLETS

8326924

020618

DAY TIME

NIGHT TIME

8326923

020718

Lot/Exp Data

Questions? 1-866-MUCINEX (1-866-682-4639)
You may also report side effects to this phone number.
Keep outer package for full information.

Maximum Strength per 4-hour dose
*DAY TIME COLD & FLU helps to relieve these
symptoms day or night; NIGHT TIME COLD & FLU
helps to relieve these symptoms at night

LIFT HERE TO OPEN



PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

3 "63824"55130" 2

Tamper evident: do not use if outer package is opened or if blister is torn or broken.

www.mucinex.com

8326925

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224, Made in England ©2018 RB 020218

Drug Facts (continued)

- 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

Drug Facts (continued)

Other information

- store between 20-25°C (68-77°F)

Inactive ingredients (Mucinex FAST-MAX DAY TIME 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 FAST-MAX

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

Do not take the Mucinex Fast-Max DAY TIME COLD & FLU and Mucinex Fast-Max NIGHT TIME COLD & FLU caplets at the same time. Always wait at least 4 hours before taking another dose of Mucinex caplets. Do not take more than a total of 12 caplets in any 24-hour period. Take only as directed. 020618 8326926

Drug Facts

Active ingredients (in each caplet)	Purposes
Mucinex FAST-MAX DAY TIME COLD & FLU	
Acetaminophen 325 mg	

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

NIGHT TIME COLD & FLU

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

Pain reliever/fever reducer
Dextromethorphan HBr 10 mg
Cough suppressant
Guafenesin 200 mg Expectorant
Phenylephrine HCl 5 mg Nasal decongestant

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

Acetaminophen 325 mg
Pain reliever/fever reducer
Diphenhydramine HCl 12.5 mg
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Drug Facts (continued)

Uses

- temporarily relieves these common cold and flu symptoms:
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 - 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

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- 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:

Drug Facts (continued)

- 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

Drug Facts (continued)

- 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)

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- 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

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

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-511
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-511-30	1 in 1 CARTON	07/28/2018	

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**MAXIMUM STRENGTH MUCINEX FAST-MAX DAY TIME COLD AND FLU**

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	200 mg
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	10 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
croscarmellose sodium (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C red no. 40 (UNII: WZB9127XOA)	
FD&C yellow no. 6 (UNII: H77VEI93A8)	
ALUMINUM OXIDE (UNII: LM26O6933)	
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
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Shape	OVAL	Size	20mm
Flavor		Imprint Code	VVV;MSC
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		2 in 1 CARTON		
1		10 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	07/28/2018	

Part 2 of 2

MAXIMUM STRENGTH MUCINEX FAST-MAX NIGHT TIME COLD AND FLU
acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet

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
croscarmellose sodium (UNII: M28OL1HH48)	
CROSPVIDONE, UNSPECIFIED (UNII: 2S7830E561)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C blue no. 2 (UNII: L06K8R7DQK)	
ALUMINUM OXIDE (UNII: LM26O6933)	
ferric oxide yellow (UNII: EX438O2MRT)	
METHACRYLIC ACID - ETHYL ACRYLATE COPOLYMER (1:1) TYPE A (UNII: NX76LV5T8J)	
mica (UNII: V8A1AW0880)	
microcrystalline cellulose (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	

POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)

sodium bicarbonate (UNII: 8MDF5V39QO)

talc (UNII: 7SEV7J4R1U)

titanium dioxide (UNII: 15FIX9V2JP)

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	VVV;CF
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 CARTON		
1		10 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	07/28/2018	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/28/2018	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2019

RB Health (US) LLC