

MUCINEX FAST-MAX DAY TIME SEVERE CONGESTION AND COUGH AND MUCINEX FAST-MAX NIGHT TIME COLD AND FLU MAXIMUM STRENGTH- dextromethorphan hydrobromide, guaifenesin, phenylephrine hydrochloride, acetaminophen, and diphenhydramine 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 Time Severe Congestion and Cough and Mucinex® Fast-Max® Night Time Cold and Flu Maximum Strength

Drug Facts

Active ingredients (in each caplet)

Mucinex FAST-MAX DAY TIME Severe Congestion & Cough

Purposes

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 25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporarily relieves **(DAY TIME only)**:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep
 - nasal congestion due to a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive **(DAY TIME only)**
- temporarily relieves these common cold and flu symptoms **(NIGHT TIME only)**:
 - nasal congestion
 - minor aches and pains
 - headache
 - sore throat

- runny nose and sneezing
- temporarily reduces fever (**NIGHT TIME only**)
- controls cough to help you get to sleep

Warnings

Liver warning (**NIGHT TIME only**)

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 that contain acetaminophen
- 3 or more alcoholic drinks daily while using this product

Sore throat warning (NIGHT TIME only**):** 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. (**NIGHT TIME only**)
- with any other drug 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.
- for children under 12 years of age

Ask a doctor before use if you have

- liver disease (**NIGHT TIME only**)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- 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 (**DAY TIME only**)
- cough that occurs with too much phlegm (mucus) (**DAY TIME only**)

Ask a doctor or pharmacist before use if you are

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

When using this product do not use more than directed. In addition, for **NIGHT TIME only**:

- excitability may occur, especially in children

- marked drowsiness may occur
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with a fever (**DAY TIME only**)
- pain, nasal congestion, or cough gets worse, or lasts more than 7 days (**NIGHT TIME only**)
- fever gets worse, or lasts more than 3 days (**NIGHT TIME only**)
- redness or swelling is present (**NIGHT TIME only**)
- new symptoms occur (**NIGHT TIME only**)
- 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. In case of overdose, get medical help or contact a Poison Control Center right away.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. (**NIGHT TIME only**)

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 older: 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 Severe Congestion & Cough)

croscarmellose sodium, FD&C Blue #2 aluminum lake, FD&C Red #40 aluminum lake, methacrylic acid-ethyl acrylate copolymer, mica, microcrystalline cellulose, polyethylene glycol 3350, polysorbate 80, polyvinyl alcohol, povidone K29/32, sodium bicarbonate, talc, titanium dioxide

Inactive ingredients (Mucinex FAST-MAX NIGHT TIME Cold & Flu)

corn starch, croscarmellose sodium, crospovidone, FD&C Blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

Questions?

1-866-MUCINEX (1-866-682-4639) You may also report side effects to this phone number.

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

Made in England

PRINCIPAL DISPLAY PANEL - Kit Carton

MAXIMUM STRENGTH*

NDC 63824-555-30

Mucinex®
FAST-MAX®

DAY TIME

Severe Congestion & Cough

Dextromethorphan HBr • Cough Suppressant
Guaifenesin • Expectorant
Phenylephrine HCl • Nasal Decongestant

- ✓ **Controls Cough**
- ✓ **Relieves Nasal & Chest Congestion**
- ✓ **Thins & Loosens Mucus**

AGES 12+

20 CAPLETS

NIGHT TIME

Cold & Flu

Acetaminophen • Pain Reliever/Fever Reducer
Diphenhydramine HCl • Antihistamine
Phenylephrine HCl • Nasal Decongestant

- ✓ **Relieves Aches, Fever & Sore Throat**
- ✓ **Relieves Nasal Congestion**
- ✓ **Relieves Runny Nose & Sneezing**

10 CAPLETS

MAXIMUM STRENGTH*

NDC 63824-555-30

Mucinex[®]

FAST-MAX[®]



**DAY
TIME**

**Severe Congestion
& Cough**

Dextromethorphan HBr • Cough Suppressant
Guaifenesin • Expectorant
Phenylephrine HCl • Nasal Decongestant



**NIGHT
TIME**

Cold & Flu

Acetaminophen • Pain Reliever/Fever Reducer
Diphenhydramine HCl • Antihistamine
Phenylephrine HCl • Nasal Decongestant

- ✓ Controls Cough
- ✓ Relieves Nasal & Chest Congestion
- ✓ Thins & Loosens Mucus

- ✓ Relieves Aches, Fever & Sore Throat
- ✓ Relieves Nasal Congestion
- ✓ Relieves Runny Nose & Sneezing

AGES **12+**

20 CAPLETS

10 CAPLETS

8142331

030714

MAXIMUM STRENGTH*

DAY TIME

NIGHT TIME

8142327

030714

LOT & EXP DATE AREA

3-63824-55530-0

***Per 4-hour dose,
dose every 4 hours**

LIFT HERE TO OPEN

Keep outer package for complete
product information.

PARENTS:

Learn about teen medicine abuse

www.StopMedicineAbuse.org

Questions?

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

You may also report side effects to
this phone number.

www.mucinex.com

LABEL
POSITION

8142329

Dist. by: Reckitt Benckiser, Parsippany, NJ 07054-0224 ©2014 RB Made in England (*Mucinex FAST-MAX DAY TIME Severe Congestion & Cough*)

030714

Drug Facts (continued)

- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not get better within 7 days or occur with a fever (*DAY TIME only*)
- pain, nasal congestion, or cough gets worse, or lasts more than 7 days (*NIGHT TIME only*)
- fever gets worse, or lasts more than 3 days (*NIGHT TIME only*)
- redness or swelling is present (*NIGHT TIME only*)
- new symptoms occur (*NIGHT TIME only*)
- cough comes back, or occurs with fever, rash, or headache that lasts.

These could be signs of a serious condition.

Drug Facts (continued)

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 older: 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 Severe*)

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

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

8152605

Do not take the Mucinex FAST-MAX DAY TIME Severe Congestion & Cough and Mucinex FAST-MAX NIGHT TIME Cold & Flu caplets at the same time. Do not take more than a total of 12 caplets in a 24-hour period. Take only as directed.

Drug Facts

Active Ingredients Purposes (in each caplet)

Mucinex FAST-MAX DAY TIME Severe Congestion & Cough

Dextromethorphan HBr 10 mg
.....Cough suppressant
Guaifenesin 200 mg.....Expectorant
Phenylephrine HCl 5 mg
.....Nasal decongestant

Active Ingredients Purposes

If pregnant or breast-feeding, ask a health professional before use. **Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. **Overdose warning:** Taking more than the recommended dose (overdose) may cause liver damage. **(NIGHT TIME only)** ▶

Congestion & Cough
 croscarmellose sodium, FD&C Blue #2 aluminum lake, FD&C Red #40 aluminum lake, methacrylic acid-ethyl acrylate copolymer, mica, microcrystalline cellulose, polyethylene glycol 3350, polysorbate 80, polyvinyl alcohol, povidone K29/32, sodium bicarbonate, talc, titanium dioxide ▶

Active ingredients Purposes
(In each caplet)
Mucinex FAST-MAX
NIGHT TIME Cold & Flu
 Acetaminophen 325 mg
Pain reliever/fever reducer
 Diphenhydramine HCl 25 mg
Antihistamine
 Phenylephrine HCl 5 mg
Nasal decongestant ▶

Drug Facts (continued)

Uses

- temporarily relieves **(DAY TIME only)**:
 - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
 - the intensity of coughing
 - the impulse to cough to help you get to sleep
 - nasal congestion due to a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive **(DAY TIME only)**
- temporarily relieves these common cold and flu symptoms **(NIGHT TIME only)**:
 - nasal congestion
 - minor aches and pains
 - headache
 - sore throat
 - runny nose and sneezing
- temporarily reduces fever **(NIGHT TIME only)**
- controls cough to help you get to sleep

Warnings

Liver warning (NIGHT TIME only): 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 ▶

Drug Facts (continued)

- with other drugs that contain acetaminophen
 - 3 or more alcoholic drinks daily while using this product
- Sore throat warning (NIGHT TIME only):** 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. **(NIGHT TIME only)**
 - with any other drug 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.
 - for children under 12 years of age ▶

Drug Facts (continued)

- Ask a doctor before use if you have**
- liver disease **(NIGHT TIME only)**
 - heart disease
 - high blood pressure
 - thyroid disease
 - diabetes
 - 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 **(DAY TIME only)**
 - cough that occurs with too much phlegm (mucus) **(DAY TIME only)**
- Ask a doctor or pharmacist before use if you are**
- taking the blood thinning drug warfarin **(NIGHT TIME only)**
 - taking sedatives or tranquilizers **(NIGHT TIME only)**
- When using this product do not use more than directed.** In addition, for **NIGHT TIME only**:
- excitability may occur, especially in children
 - marked drowsiness may occur
 - alcohol, sedatives, and tranquilizers may increase drowsiness
 - avoid alcoholic drinks ▶

Drug Facts (continued)

Inactive Ingredients
(Mucinex FAST-MAX
NIGHT TIME Cold & Flu)
 corn starch, croscarmellose sodium, crospovidone, FD&C Blue #1 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

Dist. by: Reckitt Benckiser
 Parsippany, NJ 07054-0224 ©2014 RB
 Made in England 041114

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

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

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63824-555
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Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-555-30	1 in 1 CARTON	04/25/2014	

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 DAY TIME SEVERE CONGESTION AND COUGH MAXIMUM STRENGTH

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride tablet, coated

Product Information

Route of Administration	ORAL
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Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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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)	
FD&C Blue No. 2 (UNII: L06K8R7DQK)	
aluminum oxide (UNII: LMI26O6933)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
mica (UNII: V8A1AW0880)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polyethylene glycol 3350 (UNII: G2M7P15E5P)	
polysorbate 80 (UNII: 6OZP39ZG8H)	
polyvinyl alcohol, unspecified (UNII: 532B59J990)	
povidone K30 (UNII: U725QWY32X)	
sodium bicarbonate (UNII: 8MDF5V39QO)	
talc (UNII: 7SEV7J4R1U)	
titanium dioxide (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	VV;SCC
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	03/15/2013	

Part 2 of 2

MUCINEX FAST-MAX NIGHT TIME COLD AND FLU MAXIMUM STRENGTH

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride tablet, 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	25 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)	
CROSPVIDONE (120 .MU.M) (UNII: 68401960MK)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
aluminum oxide (UNII: LMI26O6933)	
hypromellose, unspecified (UNII: 3NXW29V3WO)	
magnesium stearate (UNII: 70097M6I30)	
microcrystalline cellulose (UNII: OP1R32D61U)	
polydextrose (UNII: VH2XOU12IE)	
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
povidone, unspecified (UNII: FZ989GH94E)	
silicon dioxide (UNII: ETJ7Z6XBU4)	
stearic acid (UNII: 4ELV7Z65AP)	
titanium dioxide (UNII: 15FIX9V2JP)	
triacetin (UNII: XHX3C3X673)	

Product Characteristics

Color	BLUE	Score	no score
Shape	OVAL	Size	20mm
Flavor		Imprint Code	44;544
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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	04/30/2013	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/25/2014	

Labeler - RB Health (US) LLC (081049410)

Revised: 1/2022

RB Health (US) LLC