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

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 20 mL) ***Mucinex FAST-MAX Day Time Severe Congestion & Cough***	***Purposes***
Dextromethorphan HBr 20 mg	Cough suppressant
Guaifenesin 400 mg	Expectorant
Phenylephrine HCl 10 mg	Nasal decongestant

Active ingredients (in each 20 mL) ***Mucinex FAST-MAX Night Time Cold & Flu***	***Purposes***
Acetaminophen 650 mg	**Pain reliever/fever reducer**
Diphenhydramine HCl 25 mg	Antihistamine/cough suppressant
Phenylephrine HCl 10 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
  - cough
  - 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 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing 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
- cough that occurs with too much phlegm (mucus)

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 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 (Night Time only)

Taking more than the recommended dose (overdose) may cause liver damage. 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 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- adults and children 12 years and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other information

- each 20 mL contains: **sodium 14 mg** ***(DAY TIME only)*** and **sodium 12 mg** ***(NIGHT TIME only)***
- do not refrigerate
- store between 20-25°C (68-77°F)
- dosing cup provided

Inactive ingredients (Day Time)

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate[1], xanthan gum

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[1] may contain this ingredient

Inactive ingredients (Night Time)

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate[2], xanthan gum

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[2] may contain this ingredient

Questions?

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

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

PRINCIPAL DISPLAY PANEL - Kit Carton

NDC 63824-528-22

MAXIMUM STRENGTH*

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**

Mucinex®
FAST-MAX®

NIGHT TIME
Cold & Flu

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

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

***per 4 hour dose.**

AGE 12+ TWO – 6 fl oz (180 mL) bottles **TOTAL** – 12 fl oz (360 mL) **AGE 12+**

Drug Facts (continued)

Inactive Ingredients (Night Time)

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate,* xanthan gum

*may contain this ingredient

Tamper evident: do not use if neckband on bottle cap is broken or missing.

DO NOT TAKE THE MUCINEX FAST-MAX DAY TIME SEVERE CONGESTION & COUGH AND THE MUCINEX FAST-MAX NIGHT TIME COLD & FLU LIQUIDS AT THE SAME TIME. DO NOT TAKE MORE THAN A TOTAL OF 6 DOSES IN A 24-HOUR PERIOD. TAKE ONLY AS DIRECTED.

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

Questions?
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(1-866-682-4639)

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

NDC 63824-528-22

MAXIMUM STRENGTH*

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

Mucinex® FAST-MAX®

NIGHT TIME
Cold & Flu

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

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

*per 4 hour dose.

AGE 12+ **TWO** – 6 fl oz (180 mL) bottles **TOTAL** – 12 fl oz (360 mL) **AGE 12+**

No coating

Drug Facts (continued)

Active Ingredients (In each 20 mL) Purposes
Mucinex FAST-MAX Night Time Cold & Flu

Acetaminophen 650 mg ..... Pain reliever/fever reducer
Diphenhydramine HCl 25 mg ..... Antihistamine/cough suppressant
Phenylephrine HCl 10 mg ..... Nasal decongestant ▼

Drug Facts (continued)

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 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)***
- 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 *(Night Time only)*: Taking more than the recommended dose (overdose) may cause liver damage. 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 6 doses in any 24-hour period
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- adults and children 12 years and older: 20 mL in dosing cup provided every 4 hours
- children under 12 years of age: do not use

Other Information each 20 mL contains: **sodium 14 mg *(DAY TIME only)*** and **sodium 12 mg *(NIGHT TIME only)***
- do not refrigerate
- store between 20-25°C (68-77°F)
- dosing cup provided

Inactive Ingredients (Day Time) anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sorbitol, sucralose, trisodium citrate dihydrate*; xanthan gum *may contain this ingredient ▼

Drug Facts

Active Ingredients (In each 20 mL) Purposes
Mucinex FAST-MAX Day Time
Severe Congestion & Cough

Dextromethorphan HBr 20 mg ..... Cough suppressant
Guaifenesin 400 mg ..... Expectorant
Phenylephrine HCl 10 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
  - cough
  - 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 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing 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
- cough that occurs with too much phlegm (mucus) ▲

3-63824-52822-9

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

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

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-528

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63824-528-22	1 in 1 CARTON	05/09/2014	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	1 BOTTLE	180 mL
Part 2	1 BOTTLE	180 mL

Part 1 of 2

MUCINEX FAST-MAX SEVERE CONGESTION AND COUGH

dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride solution

Product Information	
Item Code (Source)	NDC:63824-014
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Dextromethorphan Hydrobromide (UNII: 9D2RTI9KYH) (Dextromethorphan - UNII:7355X3ROTS)	Dextromethorphan Hydrobromide	20 mg in 20 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg in 20 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 20 mL

Inactive Ingredients	
Ingredient Name	**Strength**
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propyl gallate (UNII: 8D4SNN7V92)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
trisodium citrate dihydrate (UNII: B22547B95K)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	BLUE	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:63824-014-66	180 mL in 1 BOTTLE; 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	02/07/2012	

Part 2 of 2

MAXIMUM STRENGTH MUCINEX FAST-MAX NIGHT TIME COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride solution

Product Information	
Item Code (Source)	NDC:63824-500
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	650 mg in 20 mL
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	25 mg in 20 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
anhydrous citric acid (UNII: XF417D3PSL)	
edetate disodium (UNII: 7FLD91C86K)	
FD&C Blue No. 1 (UNII: H3R47K3TBD)	
FD&C Red No. 40 (UNII: WZB9127XOA)	
glycerin (UNII: PDC6A3C0OX)	
propyl gallate (UNII: 8D4SNN7V92)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium benzoate (UNII: OJ245FE5EU)	
sorbitol (UNII: 506T60A25R)	
sucralose (UNII: 96K6UQ3ZD4)	
trisodium citrate dihydrate (UNII: B22547B95K)	
xanthan gum (UNII: TTV12P4NEE)	

Product Characteristics

Color	BLUE	**Score**	
Shape		**Size**	
Flavor	FRUIT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-500-66	180 mL in 1 BOTTLE; 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	03/15/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/09/2014	

Labeler - RB Health (US) LLC (081049410)

Revised: 12/2018 RB Health (US) LLC