

**MUCINEX FAST-MAX DAY COLD AND FLU AND NIGHT COLD AND FLU MAXIMUM STRENGTH- acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, 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.*

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**Mucinex® Fast-Max® Day Cold & Flu and Night Cold & Flu Maximum Strength**

***Drug Facts***

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***Active ingredients (in each liquid gel)***

***Mucinex FAST-MAX DAY Cold & Flu***

***Purposes***

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<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 10 mg	Cough suppressant
Guaifenesin 200 mg	Expectorant
Phenylephrine HCl 5 mg	Nasal decongestant

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***Active ingredients (in each liquid gel)***

***Mucinex FAST-MAX NIGHT Cold & Flu***

***Purposes***

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<b>Acetaminophen 325 mg</b>	<b>Pain reliever/fever reducer</b>
Dextromethorphan HBr 10 mg	Cough suppressant
Doxylamine succinate 6.25 mg	Antihistamine
Phenylephrine HCl 5 mg	Nasal decongestant

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**Uses**

- temporarily relieves these common cold and flu symptoms:
  - sinus congestion and pressure
  - cough
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - runny nose (***NIGHT only***)
  - sneezing (***NIGHT only***)
  - itching of the nose or throat (***NIGHT only***)
  - itchy, watery eyes due to hay fever (***NIGHT only***)

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (**DAY 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 liquid gels 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
- trouble urinating due to an enlarged prostate gland
- glaucoma (**NIGHT only**)
- a breathing problem such as emphysema or chronic bronchitis (**NIGHT 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 only**)

**When using this product**

- **do not use more than directed**
- excitability may occur, especially in children (**NIGHT only**)
- marked drowsiness may occur (**NIGHT only**)
- alcohol, sedatives, and tranquilizers may increase drowsiness (**NIGHT only**)
- avoid alcoholic drinks (**NIGHT only**)
- be careful when driving a motor vehicle or operating machinery (**NIGHT 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 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

**Other information**

- store at 20-25°C (68-77°F)
- avoid excessive heat

**Inactive ingredients (DAY only)**

FD&C yellow no. 6, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

## **Inactive ingredients (NIGHT only)**

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

## **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 Dissolving Liquid Gels!

NDC 72854-129-24

MAXIMUM STRENGTH

Mucinex®

FAST-MAX®

DAY

COLD & FLU

Acetaminophen- Pain Reliever/

Fever Reducer

Dextromethorphan HBr - Cough Suppressant

Guaifenesin - Expectorant

Phenylephrine HCl - 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+

16

LIQUID GELS

(Liquid Filled)

Capsules)

NIGHT  
COLD & FLU

Acetaminophen – Pain Reliever/  
Fever Reducer  
Dextromethorphan HBr – Cough Suppressant  
Doxylamine succinate – Antihistamine  
Phenylephrine HCl – Nasal Decongestant

HEADACHE  
SORE THROAT  
ITCHY THROAT  
BODY PAIN  
FEVER  
COUGH

ALL IN  
ONE\*

NASAL CONGESTION  
SNEEZING  
RUNNY NOSE

ACTUAL SIZE

8  
LIQUID GELS  
(Liquid Filled  
Capsules)

TOTAL 24  
LIQUID GELS

MAXIMUM STRENGTH



VALUE PACK

24 LIQUID GELS

DAY COLD & FLU

NIGHT COLD & FLU

Tamper evident: Do not use if carton is damaged or if printed seal on blister is broken or missing.

Fast Dissolving Liquid Gels!

MAXIMUM STRENGTH

NDC 72854-129-24



DAY COLD & FLU

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

NIGHT COLD & FLU

Acetaminophen - Pain Reliever/ Fever Reducer
Dextromethorphan HBr - Cough Suppressant
Doxylamine succinate - Antihistamine
Phenylephrine HCl - Nasal Decongestant



FOR AGES 12+

ACTUAL SIZE



ACTUAL SIZE



16 LIQUID GELS (Liquid Filled Capsules)

TOTAL 24 LIQUID GELS

8 LIQUID GELS (Liquid Filled Capsules)

HEALTH • HYGIENE • HOME
www.mucinex.com
Patent: www.rb.com/patents
Dist. by: RB Health (US)
Parsippany, NJ 07054-0224
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3179618 032821



LOT:
EXP.:
3179618





### Drug Facts

#### Active ingredients (in each liquid gel)

#### Mucinex FAST-MAX DAY 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

#### Purposes

#### Active ingredients (in each liquid gel)

#### Mucinex FAST-MAX NIGHT Cold & Flu

Acetaminophen 325 mg.....	Pain reliever/fever reducer
Dextromethorphan HBr 10 mg.....	Cough suppressant
Doxylamine succinate 6.25 mg.....	Antihistamine
Phenylephrine HCl 5 mg.....	Nasal decongestant

#### Purposes

#### Uses

- temporarily relieves these common cold and flu symptoms:
  - sinus congestion and pressure
  - cough
  - headache
  - sore throat
  - sneezing (NIGHT only)
  - itching of the nose or throat (NIGHT only)
  - itchy, watery eyes due to hay fever (NIGHT only)
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive (DAY 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 liquid gels 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,

### Drug Facts (continued)

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
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland
- glaucoma (NIGHT only)
- a breathing problem such as emphysema or chronic bronchitis (NIGHT 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 only)

#### When using this product

- do not use more than directed
- excitability may occur, especially in children (NIGHT only)
- marked drowsiness may occur (NIGHT only)
- alcohol, sedatives, and tranquilizers may increase drowsiness (NIGHT only)
- avoid alcoholic drinks (NIGHT only)
- be careful when driving a motor vehicle or operating machinery (NIGHT 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 liquid gels in any 24-hour period
- adults and children 12 years of age and over: take 2 liquid gels every 4 hours
- children under 12 years of age: do not use

#### Other information

- store at 20-25°C (68-77°F)
- avoid excessive heat

### Drug Facts (continued)

#### Inactive ingredients (DAY only)

FD&C yellow no. 6, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

#### Inactive ingredients (NIGHT only)

D&C yellow no. 10, FD&C blue no. 1, gelatin, glycerin, hypromellose, isopropyl alcohol, lecithin, light mineral oil, polyethylene glycol, povidone, propylene glycol, sorbitol sorbitan solution, titanium dioxide, water

#### Questions?

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

You may also report side effects to this phone number.

\*DAY COLD & FLU helps to relieve these symptoms day or night; NIGHT COLD & FLU helps to relieve these symptoms at night!

#### Maximum Strength per 4-hour dose

Do not take the Mucinex Fast-Max DAY COLD & FLU and Mucinex Fast-Max NIGHT COLD & FLU liquid gels at the same time. Always wait at least 4 hours before taking another dose of Mucinex liquid gels. Do not take more than a total of 12 liquid gels in any 24-hour period.

Take only as directed.

Keep carton for full information.

## PARENTS:

Learn about teen medicine abuse

[www.StopMedicineAbuse.org](http://www.StopMedicineAbuse.org)

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

acetaminophen, dextromethorphan hydrobromide, guaifenesin, doxylamine succinate, and

phenylephrine hydrochloride kit

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72854-129
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## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-129-24	1 in 1 CARTON	07/26/2021	

## Quantity of Parts

Part #	Package Quantity	Total Product Quantity
<b>Part 1</b>	2 BLISTER PACK	16
<b>Part 2</b>	1 BLISTER PACK	8

## Part 1 of 2

### MUCINEX FAST-MAX COLD AND FLU MAXIMUM STRENGTH

acetaminophen, dextromethorphan hydrobromide, guaifenesin, and phenylephrine hydrochloride capsule, liquid filled

## Product Information

<b>Item Code (Source)</b>	NDC:72854-126
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<b>Route of Administration</b>	ORAL
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## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>GUAIFENESIN</b> (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>FD&amp;C YELLOW NO. 6</b> (UNII: H77VEI93A8)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	



<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Product Characteristics

<b>Color</b>	orange	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	24mm
<b>Flavor</b>		<b>Imprint Code</b>	AR01
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72854-126-24	8 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	07/26/2021	

## Part 2 of 2

### MUCINEX FAST MAX NIGHT COLD AND FLU

acetaminophen, dextromethorphan hbr, doxylamine succinate, phenylephrine hci capsule, liquid filled

### Product Information

<b>Item Code (Source)</b>	NDC:72854-132
<b>Route of Administration</b>	ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RT19KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
<b>DOXYLAMINE SUCCINATE</b> (UNII: V9B19B5Y12) (DOXYLAMINE - UNII:95QB77JKPL)	DOXYLAMINE SUCCINATE	6.25 mg
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1VS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>ISOPROPYL ALCOHOL</b> (UNII: ND2M416302)	
<b>LIGHT MINERAL OIL</b> (UNII: N6K5787QVP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>WATER</b> (UNII: 059QF0KOOR)	

## Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	21mm
<b>Flavor</b>		<b>Imprint Code</b>	AR03
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		8 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	07/26/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/26/2021	

**Labeler** - RB Health (US) LLC (081049410)