MUCINEX FAST-MAX DAY TIME SEVERE CONGESTION AND COUGH - 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 - 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 12.5 mg	Antihistamine/cough suppressant
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
  - 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):***
  - cough
  - minor aches and pains
  - headache
  - nasal congestion
  - sore throat
  - runny nose
  - sneezing
  - itching of the nose or throat
  - itchy, watery eyes due to hay fever
- 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 containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

Allergy alert (NIGHT TIME only)

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 (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 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 ***(NIGHT TIME only)***
- 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 ***(NIGHT TIME only)***
- 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
- 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 lasts more than 7 days, 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 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 at 20-25°C (68-77°F)

Inactive ingredients (Mucinex FAST-MAX DAY TIME SEVERE CONGESTION & COUGH)

croscarmellose sodium, FD&C blue no. 2 aluminum lake, FD&C red no. 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)

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

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 Made in England

PRINCIPAL DISPLAY PANEL - Kit Carton

MAXIMUM STRENGTH

DAY TIME
NIGHT TIME

MAXIMUM STRENGTH
NDC 63824-558-30

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

NIGHT
TIME
COLD & FLU

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

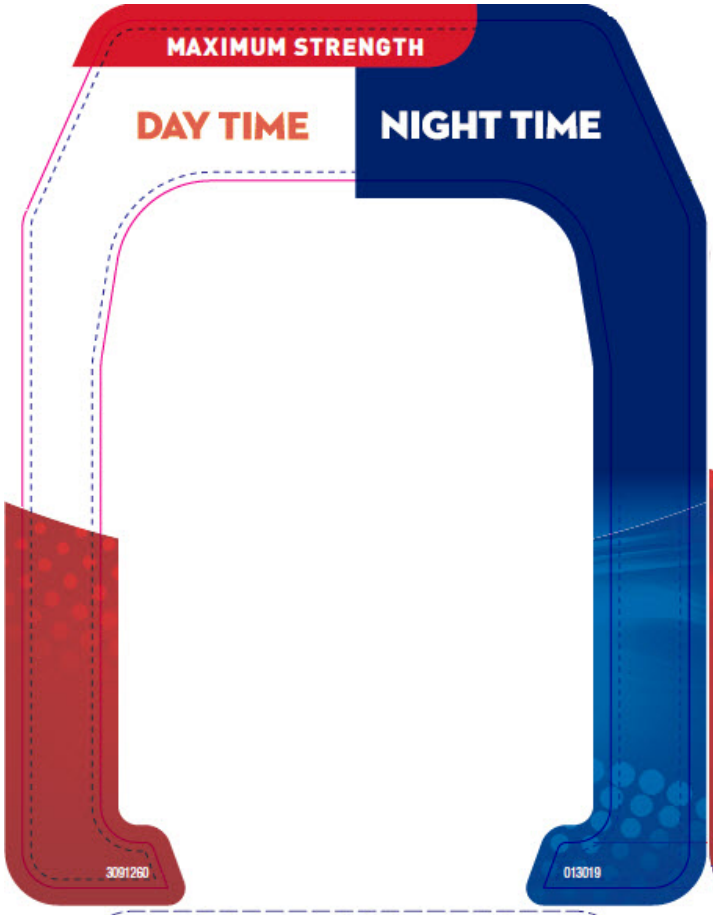
- Relieves Aches, Fever & Sore Throat
- Controls Cough
- Relieves Nasal Congestion
- Relieves Runny Nose & Sneezing

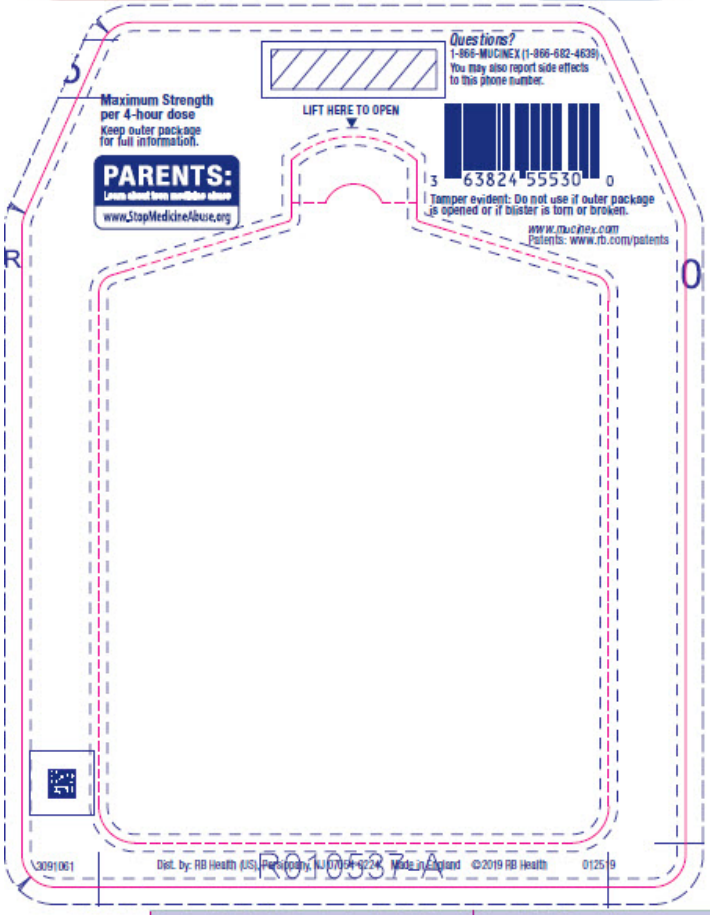
20 CAPLETS

30 TOTAL
FOR AGES 12+

10 CAPLETS

3091260
013019





Drug Facts

Active ingredients (in each caplet)	Purposes
Mucinex FAST-MAX DAY TIME SEVERE CONGESTION & COUGH	

Drug Facts (continued)

- temporarily relieves these common cold and flu symptoms *(NIGHT TIME only)*:
  - cough
  - minor aches and pains
  - headache
  - nasal congestion

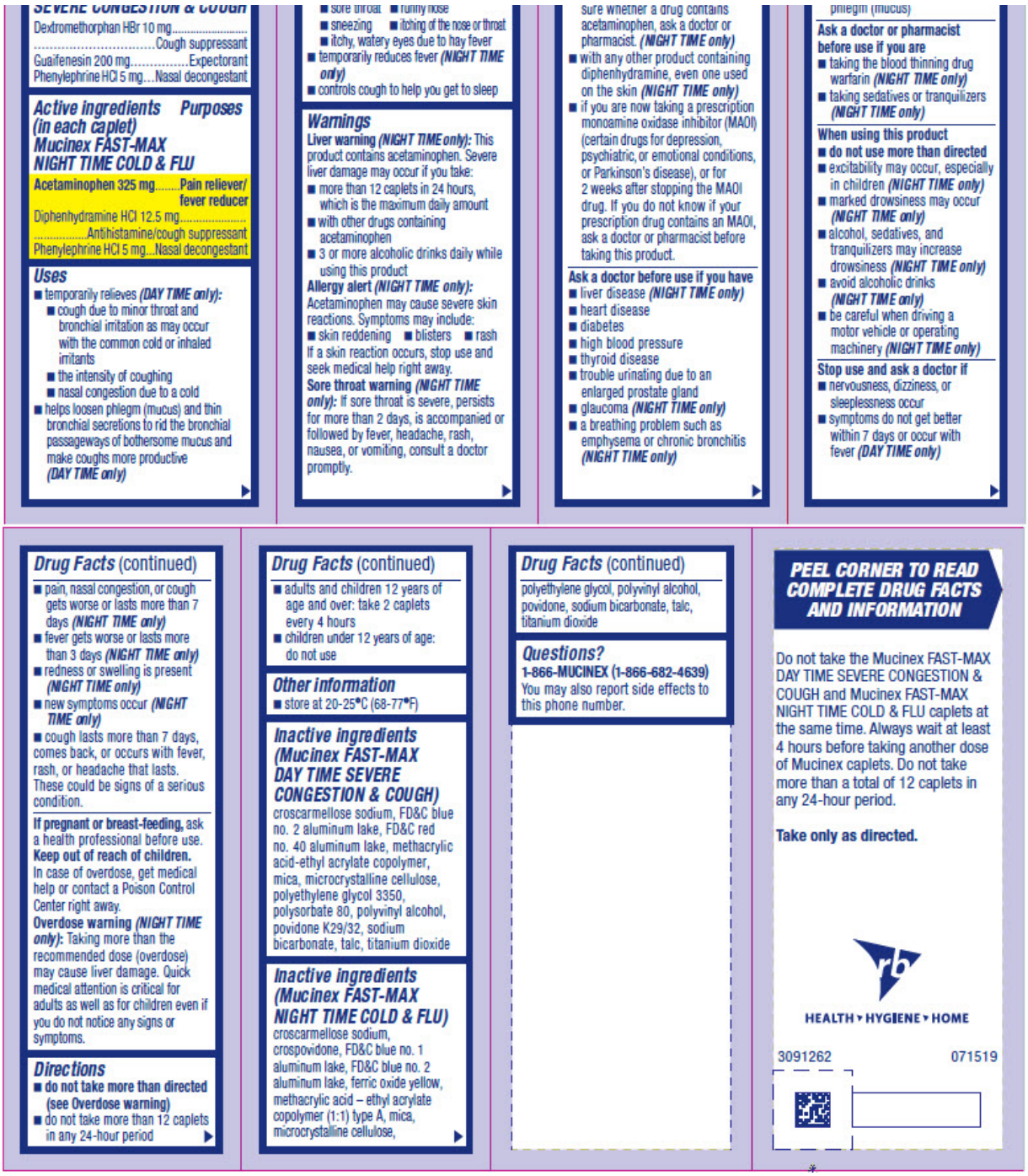
Drug Facts (continued)

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not

Drug Facts (continued)

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



MUCINEX FAST-MAX DAY TIME SEVERE CONGESTION AND COUGH - 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:63824-558

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:63824-558-30	1 in 1 CARTON	08/25/2015	

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

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
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	ORANGE	**Score**	no score

Shape	OVAL	**Size**	20mm
Flavor		**Imprint Code**	VVV;SCC
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	08/25/2015	

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	12.5 mg
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg

Inactive Ingredients

Ingredient Name	Strength
croscarmellose sodium (UNII: M28OL1HH48)	
crospovidone (15 mpa.s at 5%) (UNII: 68401960MK)	
FD&C blue no. 1 (UNII: H3R47K3TBD)	
FD&C blue no. 2 (UNII: L06K8R7DQK)	
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 K30 (UNII: U725QWY32X)	
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;SI
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	08/25/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/25/2015	

Labeler - RB Health (US) LLC (081049410)

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