MUCINEX DM MAXIMUM STRENGTH- guaifenesin and dextromethorphan hydrobromide tablet, extended release
RB Health (US) LLC

Mucinex®DM

Drug Facts

Active ingredients (in each extended-release tablet)
Dextromethorphan HBr 60 mg
Guaifenesin 1200 mg

Active ingredients (in each extended-release tablet)	***Purposes***
Dextromethorphan HBr 60 mg	Cough suppressant
Guaifenesin 1200 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - 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

Warnings

Do not use

- for children under 12 years of age
- 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

- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product

- do not use more than directed

Stop use and ask a doctor if

- cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

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.

Directions

- do not crush, chew, or break extended-release tablet
- take with a full glass of water
- this product can be administered without regard for timing of meals
- adults and children 12 years and older: 1 extended-release tablet every 12 hours; not more than 2 extended-release tablets in 24 hours
- children under 12 years of age: do not use

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B; D&C yellow no. 10 aluminum lake; hypromellose, USP; magnesium stearate, NF; microcrystalline cellulose, NF; sodium starch glycolate, NF

Questions?

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

Dist. by: RB Health (US)
Parsippany, NJ 07054-0224

Made in England

PRINCIPAL DISPLAY PANEL - 14 Tablet Blister Pack Carton

NDC 63824-072-35
MAXIMUM STRENGTH

Mucinex®DM
1200 mg guaifenesin & 60 mg dextromethorphan HBr
extended-release tablets

EXPECTORANT & COUGH SUPPRESSANT

12
HOUR ®

- Controls Cough
- Thins and Loosens Mucus
- Immediate and Extended Release

14
EXTENDED-RELEASE TABLETS

MUCINEX DM MAXIMUM STRENGTH

guaifenesin and dextromethorphan hydrobromide tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63824-072
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	

MAGNESIUM STEARATE (UNII: 70097M6I30)	

Product Characteristics

Color	white (yellow and white)	**Score**	no score
Shape	OVAL	**Size**	22mm
Flavor		**Imprint Code**	Mucinex;1200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63824-072-07	1 in 1 CARTON	06/26/2012	
1		7 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63824-072-35	1 in 1 CARTON	06/26/2012	
2		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63824-072-36	2 in 1 CARTON	06/26/2012	
3		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:63824-072-46	3 in 1 CARTON	06/26/2012	
4		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
5	NDC:63824-072-48	4 in 1 CARTON	06/26/2012	
5		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
6	NDC:63824-072-18	2 in 1 CARTON	06/26/2012	06/15/2022
6		9 in 1 BLISTER PACK; Type 0: Not a Combination Product		
7	NDC:63824-072-56	4 in 1 CARTON	07/01/2021	
7		14 in 1 BLISTER PACK; Type 0: Not a Combination Product		
8	NDC:63824-072-02	1 in 1 CARTON	08/01/2021	
8		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA021620	06/26/2012	

Labeler - RB Health (US) LLC (081049410)