TOPCARE MUCUS DM- dextromethorphan hbr, guaifenes in tablet, extended release Topco Associates LLC

Topco Associates LLC. Mucus DM Drug Facts

Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 60 mg

Guaifenesin 1200 mg

Purposes

Cough suppressant

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 (1-800-222-1222).

Directions

- do not crush, chew, or break 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 tablet every 12 hours; not more than 2 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- each tablet contains: magnesium 25 mg
- do not use if printed foil under cap is broken or missing
- store between 20-25°C (68-77°F)

Inactive ingredients

carbomer homopolymer type B, copovidone, D&C yellow #10 aluminum lake, hypromellose, magnesium hydroxide, magnesium stearate, microcrystalline cellulose, silicon dioxide

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO MAXIMUM STRENGTH MUCINEX® DM ACTIVE INGREDIENTS

MAXIMUM STRENGTH

Mucus DM

GUAIFENESIN 1200 mg & DEXTROMETHORPHAN HYDROBROMIDE 60 mg

EXTENDED-RELEASE TABLETS

EXPECTORANT/COUGH SUPPRESSANT

12 HOUR

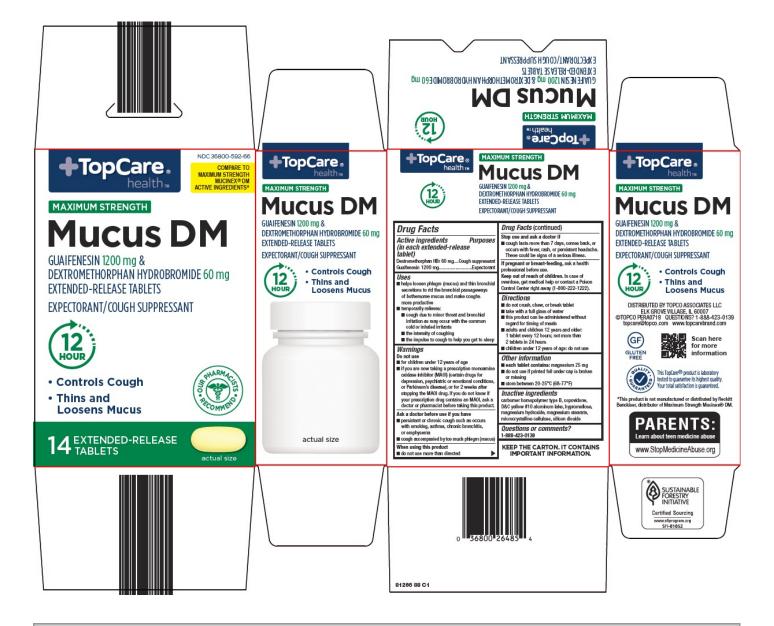
Controls Cough

Thins and Loosens Mucus

OUR PHARMACISTS RECOMMEND

14 EXTENDED-RELEASE TABLETS

actual size



TOPCARE MUCUS DM

dextromethorphan hbr, guaifenesin tablet, extended release

Product Information	duct Information		
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-592
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	1200 mg	
DEXTRO METHO RPHAN HYDRO BRO MIDE (UNII: 9 D2RTI9 KYH) (DEXTROMETHO RPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	60 mg	

Inactive Ingredients		
Ingredient Name	Strength	
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: HHT01ZNK31)		
COPOVIDONE K25-31 (UNII: D9 C330 MD8 B)		
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)		
HYPROMELLOSES (UNII: 3NXW29 V3WO)		
MAGNESIUM HYDRO XIDE (UNII: NBZ3QY004S)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
CELLULO SE, MICRO CRYSTALLINE (UNII: OP1R32D61U)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		

Product Characteristics			
Color	YELLOW (light)	Score	no score
Shape	OVAL	Size	22mm
Flavor		Imprint Code	L812
Contains			

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-592-66	1 in 1 CARTON	09/06/2018	
1	14 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207602	09/06/2018	

Labeler - Topco Associates LLC (006935977)

Revised: 9/2018 Topco Associates LLC