

TOPCARE MUCUS DM- dextromethorphan hydrobromide, guaifenesin tablet, extended release
Topco Associates LLC

Topco Associates LLC. Mucus DM Drug Facts

Active ingredients (in each extended-release tablet)

Dextromethorphan HBr 30 mg

Guaifenesin 600 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 or 2 tablets every 12 hours; not more than 4 tablets in 24 hours
- children under 12 years of age: do not use

Other information

- **each tablet contains:** magnesium 15 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

TopCare® health

COMPARE TO MUCINEX® DM ACTIVE INGREDIENTS

Mucus DM

GUAIFENESIN 600 mg

DEXTROMETHORPHAN HYDROBROMIDE 30 mg

EXTENDED-RELEASE TABLETS

EXPECTORANT/COUGH SUPPRESSANT

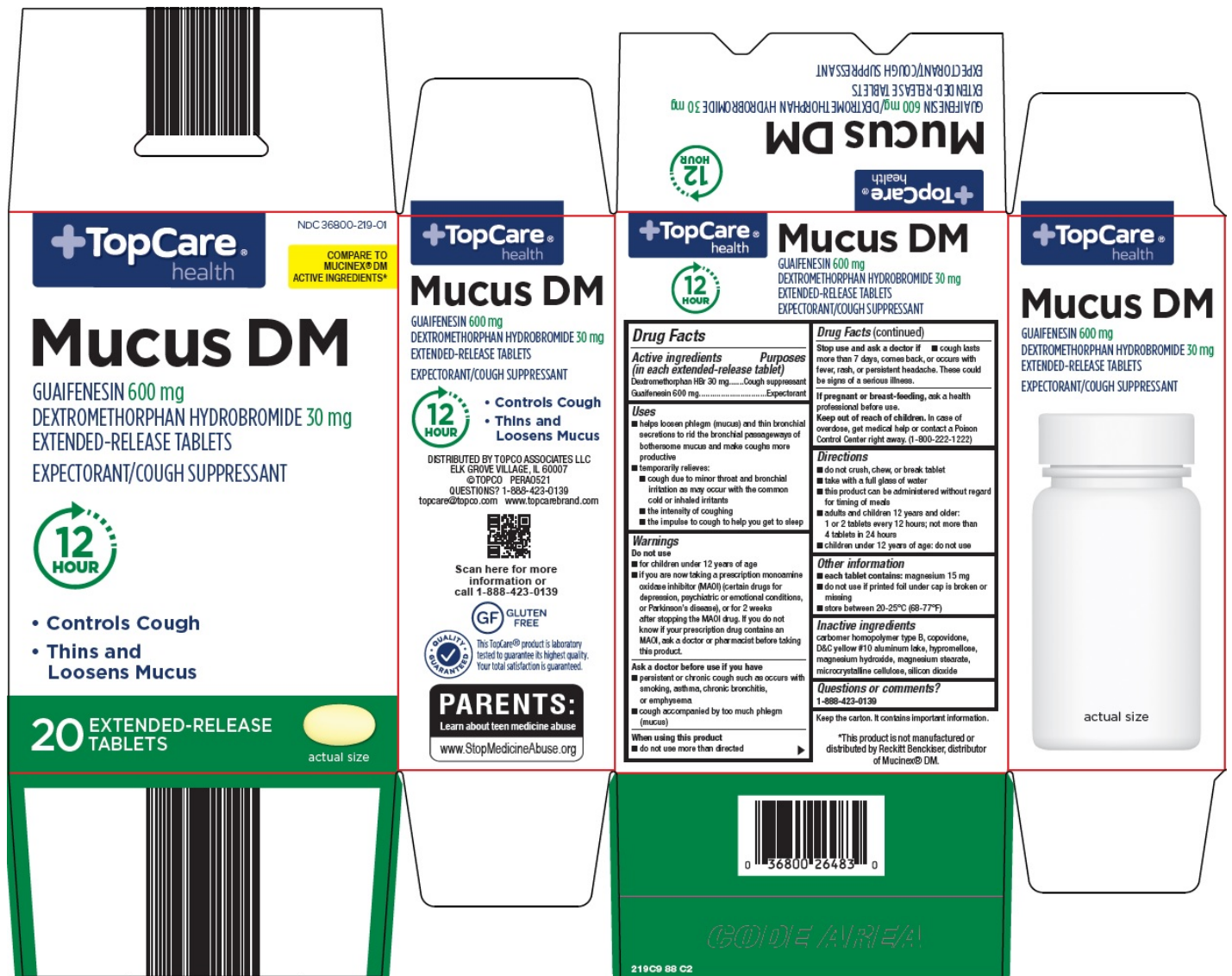
12 HOUR

• Controls Cough

• Thins and Loosens Mucus

20 EXTENDED-RELEASE TABLETS

actual size



TOPCARE MUCUS DM

dextromethorphan hydrobromide, guaifenesin tablet, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-219
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	30 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	600 mg

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER TYPE B (ALLYL PENTAERYTHRITOL OR ALLYL SUCROSE CROSSLINKED) (UNII: K6MOM3T5YL)	
COPOVIDONE K25-31 (UNII: D9C330MD8B)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM HYDROXIDE (UNII: NBZ3QY004S)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	YELLOW	Score	no score
Shape	OVAL	Size	16mm
Flavor		Imprint Code	L219;600
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-219-01	1 in 1 CARTON	07/10/2019	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-219-49	1 in 1 CARTON	04/13/2022	
2		40 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	07/10/2019	

