

TOPCARE TUSSIN DM MAX- dextromethorphan hbr, guaifenesin solution
Topco Associates 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.

Topco Associates LLC. Tussin DM Max Drug Facts

Active ingredients (in each 20 mL)

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 400 mg

Purposes

Cough suppressant

Expectorant

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a cold
- helps loosen phlegm (mucus) and thin bronchial secretions to drain bronchial tubes

Warnings

Do not use

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

- cough that occurs with too much phlegm (mucus)
- cough that lasts or is chronic such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if

cough lasts for more than 7 days, comes back, or is accompanied by fever, rash, or persistent headache. A persistent cough may be a sign 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 (1-800-222-1222).

Directions

- do not take more than 6 doses in any 24-hour period
- measure only with dosing cup provided
- keep dosing cup with product
- mL = milliliter
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	20 mL every 4 hours
children under 12 years	do not use

Other information

- **each 20 mL contains:** sodium 13 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

acetic acid, anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, flavor, glycerin, menthol, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

TopCare® health

COMPARE TO ROBITUSSIN® MAXIMUM STRENGTH COUGH + CHEST CONGESTION DM
ACTIVE INGREDIENTS

PEAK COLD

NON-DROWSY

Tussin DM Max

Cough & Chest Congestion DM

COUGH SUPPRESSANT-DEXTROMETHORPHAN HBr

EXPECTORANT-GUAIFENESIN

MAXIMUM STRENGTH

RELIEVES:

- Cough
- Mucus

Adult

For Ages 12 & Over

4 FL OZ (118 mL)

RASPBERRY MENTHOL FLAVOR



TOPCARE TUSSIN DM MAX

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-847
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	20 mg in 20 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg in 20 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-847-26	1 in 1 CARTON	09/26/2018	
1		118 mL in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:36800-847-34	1 in 1 CARTON	09/26/2018	
2		237 mL in 1 BOTTLE; 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	09/26/2018	

Labeler - Topco Associates LLC (006935977)

Revised: 8/2022

Topco Associates LLC