

**TOPCARE TAB TUSSIN DM- dextromethorphan hydrobromide /
guaifenesin tablet
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.

Drug Facts TOPCARE Tab Tussin DM

Active ingredient - (per tablet)

Dextromethorphan Hydrobromide 20mg Cough Suppressant

Guaifenesin 400mg Expectorant

Ask doctor before use

If you have persistent or chronic cough, such as occurs with smoking, asthma, bronchitis or emphysema

cough is accompanied by excessive phlegm (mucous)

Stop use and ask doctor if

Symptoms are accompanied by fever, rash or persistent headache

cough persists for more than 1 week or tends to recur

A persistent cough may be a sign of a serious condition

Do not use

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 MAOI drug, If you do not know if your prescription drug contains

an MAOI, ask your doctor or pharmacist before using this product.

Keep out of reach of children,

In case of overdose, get medical help or contact a Poison Center immediately

Pregnant or breastfeeding

If pregnant or breastfeeding, ask a health professional before use.

Inactive ingredients

magnesium stearate, maltodextrin, microcrystalline cellulose, povidone K30, povidone 90F, silicon dioxide, stearic acid.

Directions

- Adults and children 12 years of age and over:
take 1 tablet every 4 hours as needed
 - Children 6 to 12 years of age: take 1/2 tablet every 4 hours as needed
 - Children under 6 years of age: consult a doctor
- Do not exceed 6 doses in a 24 hour period or as directed by a doctor
Other information store at 15°- 30° C (59°- 86°F) Rev 10/U9 RCCF

Uses

- temporarily relieves cough due to minor throat and bronchial irritation as may occur with a common cold
- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus
- helps make coughs more productive

Purpose

Cough Suppressant

Expectorant

Warning

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Display panel



TOPCARE TAB TUSSIN DM

dextromethorphan hydrobromide / guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-442
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

Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)

Guaifenesin

400 mg

Inactive Ingredients

Ingredient Name	Strength
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POVIDONE K30 (UNII: U725QWY32X)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	2 pieces
Shape	OVAL	Size	17mm
Flavor		Imprint Code	PH073
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-442-24	2 in 1 CARTON	05/06/2021	
1		12 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	05/06/2021	

Labeler - TOPCO ASSOCIATES LLC (006935977)**Registrant** - Reese Pharmaceutical Co (004172052)**Establishment**

Name	Address	ID/FEI	Business Operations
Reese Pharmaceutical Co		004172052	relabel(36800-442) , repack(36800-442)

Revised: 5/2021

TOPCO ASSOCIATES LLC