TOPCARE CHEST CONGESTION AND COUGH RELIEF 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 CVS Congestion Relief 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 emphysma

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 if you are now taking a prescription monoamine oxidase (inhiMor~MAIO)

Certain drugs for depression, psychiatric or emotional conditioners or Parkinson's disease

or for 2 weeks after stopping MAIO drug, If you do not know if your prescription drug contains

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

Keep out of reach of children, In ase of overdose, get medical help or contact a Poison Center immediately

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

magnesium stearate, microcrystalline cellulose, colloidal silicon dioxide, (co) povidone, dicalcium phosphate, maltodextrin, sodium starch glycolate, stearic acid

Directions

- Adults and children 12 years of age and over:
- take 1 tablet every 4 hours as needed
- Children 610 under 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

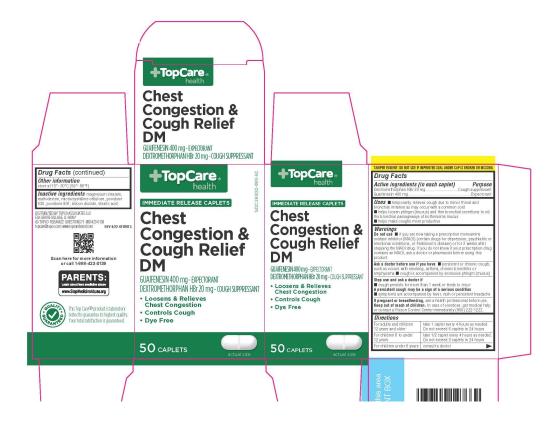
Expectorant

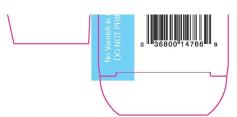
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dextromethorphan hydrobromide / guaifenesin tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-988
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)				
COPOVIDONE (UNII: D9C330MD8B)				
MALTODEXTRIN (UNII: 7CVR7L4A2D)				
STEARIC ACID (UNII: 4ELV7Z65AP)				

Product Characteristics				
Color	white	Score	2 pieces	
Shape	OVAL	Size	17mm	

Flavor	I	Imprint Code	PH073
Contains			

ı	Packaging					
	# Item Code	Package Description	Marketing Start Date	Marketing End Date		
	1 NDC:36800- 988-50	1 in 1 CARTON	01/28/2010			
	1	30 in 1 BOTTLE, PLASTIC; 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	12/07/2009		

Labeler - TOPCO ASSOCIATES LLC (006935977)

Registrant - Reese Pharmaceutical Co (004172052)

Revised: 12/2022 TOPCO ASSOCIATES LLC