

MUCUS RELIEF DM- dextromethorphan hbr/guaifenesin tablet
KROGER COMPANY

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.

280R - KROGER MUCUS RELIEF DM

Each immediate-release tablet contains
Dextromethorphan HBr 20 mg Guaifenesin 400 mg

Colloidal Silicon Dioxide, Magnesium Stearate, Maltodextrin, Microcrystalline Cellulose, Povidone, Silicon Dioxide, Sodium Starch Glycolate, Stearic Acid

Expectorant – Cough Suppressant

Helps loosen phlegm (mucus)
Helps thin bronchial secretions to make coughs more productive
Temporarily relieves cough due to minor throat and bronchial irritation associated with the common cold

Directions: Adults and children 12 years of age and older, take 1 tablet every 4 hours with a full glass of water while symptoms persist. Do not exceed 6 doses in 24 hours.
Children under 12 years of age do not use.

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.

Keep Out of Reach of Children: In case of overdose, get medical help or contact a Poison Control Center

dextromethorphan hbr/guaifenesin tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-280
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
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	TCL280
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-280-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	06/03/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	06/03/2019	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(41226-280)

Revised: 5/2019

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