MUCUS RELIEF COUGH AND CONGESTION DM- guaifenesin and dextromethorphan hbr tablet
Bryant Ranch Prepack

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.

Guaifenesin 400 mg - DextromethorphanCaplets 20 mg Caplets

Active ingredients (in each caplet)

Dextromethorphan HBr 20 mg
Guaifenesin 400 mg

Purpose

Cough suppressant
Expectorant

Uses

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

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 accompanied by too much phlegm (mucus)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

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 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.

Directions

- take with a full glass of water
- **adults and children 12 years of age and over:** 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- **children under 12 years:** do not use

Other information

- store at 15º-30ºC (59º-86ºF)

Inactive ingredients

Colloidal silicon dioxide, magnesium stearate, maltodextrin, microcrystalline cellulose, povidone, stearic acid

Questions or comments?

call 804-270-4498, 8.30 am-4.30 pm ET, Monday - Friday
TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

HOW SUPPLIED

NDC: 71335-1928-1: 30 Tablets in a BOTTLE

NDC: 71335-1928-2: 20 Tablets in a BOTTLE

NDC: 71335-1928-3: 18 Tablets in a BOTTLE

Guaifenesin/DM 400/20mg Tablet

MUCUS RELIEF COUGH AND CONGESTION DM

guaifenesin and dextromethorphan hbr tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71335-1928(NDC:54738-985)
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)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

STEARIC ACID (UNII: 4ELV7Z65AP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	17mm
Flavor		**Imprint Code**	AP;150
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71335-1928-1	30 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2021	
2	NDC:71335-1928-2	20 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2021	
3	NDC:71335-1928-3	18 in 1 BOTTLE; Type 0: Not a Combination Product	08/11/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	04/01/2016	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(71335-1928) , RELABEL(71335-1928)

Revised: 8/2021 Bryant Ranch Prepack