

ROBAFEN DM- dextromethorphan hbr, guaifenesin solution

Major Pharmaceuticals

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.

Major Pharmaceuticals Robafen® DM Drug Facts

Active ingredients (in each 10 mL)

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 200 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	10 mL every 4 hours
children under 12 years	do not use

Other information

- **Phenylketonurics:Contains Phenylalanine 30 mg per 10 mL**
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

aspartame, benzoic acid, flavor, glycerin, hydroxyethyl cellulose, menthol, polyethylene glycol, purified water

Questions or comments?

1-800-616-2471

Principal Display Panel

ROBAFEN[®] DM COUGH

SUGAR-FREE

CLEAR

COUGH SUPPRESSANT (Dextromethorphan HBr)

EXPECTORANT (Guaifenesin)

Relieves:

Cough

Chest Congestion

Non-Drowsy

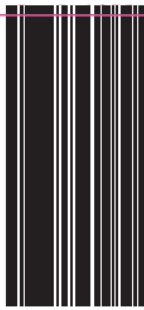
Specially Formulated For DIABETICS

COMPARE TO the active ingredients of ROBITUSSIN[®] SUGAR-FREE COUGH + CONGESTION DM

FOR ADULTS

Ages 12 and Over

4 FL. OZ. (118 mL)



NDC 0904-6759-20

MAJOR®

ROBAFEN®

DM COUGH SUGAR-FREE

CLEAR

COUGH SUPPRESSANT (Dextromethorphan HBr)
EXPECTORANT (Guaifenesin)

Relieves:

- Cough
- Chest Congestion

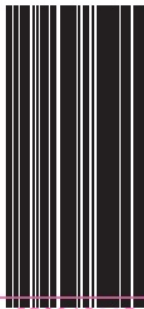
Non-Drowsy

Specially Formulated For
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CLEAR

DM COUGH SUGAR-FREE

ROBAFEN®

MAJOR®

Drug Facts

Active ingredients *Purposes*
(in each 10 mL)
Dextromethorphan HBr,
USP 20 mg.....Cough suppressant
Guaifenesin, USP 200 mg.....Expectorant

Uses

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Drug Facts (continued)

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Inactive ingredients aspartame, benzoic acid, flavor, glycerin, hydroxyethyl cellulose, menthol, polyethylene glycol, purified water

Questions or comments?
1-800-616-2471

Gluten Free

*This product is not manufactured or distributed by Pfizer, distributor of Robitussin® Sugar-Free Cough + Chest Congestion DM.

DO NOT USE IF PRINTED NECKBAND IS BROKEN OR MISSING

Distributed by
MAJOR® PHARMACEUTICALS
17177 N Laurel Park Drive, Suite 233
Livonia, MI 48152
M-05 REV. 07/18
Re-Order No. 700959

Dosing Cup Included

PARENTS:

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LOT NO.

EXP.

: 57826 5C C7

ROBAFEN DM

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0904-6759
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 10 mL
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
ASPARTAME (UNII: Z0H242BBR1)	
BENZOIC ACID (UNII: 8SKN0B0MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
WATER (UNII: 059QF0K00R)	
MENTHOL (UNII: L7T10EIP3A)	

Product Characteristics

Color		Score	
Shape		Size	
Flavor	CHERRY	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-6759-20	1 in 1 CARTON	11/29/2018	
1		118 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	11/29/2018	

Labeler - Major Pharmaceuticals (191427277)

Revised: 11/2018

Major Pharmaceuticals