

ROBAFEN DM- dextromethorphan hydrobromide, guaifenesin solution
Preferred Pharmaceuticals Inc.

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 20 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	20 mL every 4 hours
children under 12 years	do not use

Other information

- **each 20 mL contains:** sodium 14 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum

Questions or comments?

1-800-616-2471

Package/Label Principal Display Panel

MAJOR[®]

Relabeled By: Preferred Pharmaceuticals Inc.

Compare to Robitussin[®] Cough + Chest Congestion DM active ingredients

Robafen[®] DM Cough and Chest Congestion

Dextromethorphan HBr, USP 20 mg

Guaifenesin, USP 200 mg

Cough Suppressant

Expectorant

Controls Cough
 Relieves Chest Congestion
 Thins and Loosens Mucus
 SEE NEW DOSING
 Raspberry Flavor
 Non-Drowsy
 For Adults Ages 12 and Over
 4 FL. OZ. (118 mL)


**Robafen® DM
Cough & Chest
Congestion**

Generic for Robitussin DM

In each teaspoonful (20mL):
 Dextromethorphan HBr 20mg...Cough
 Suppressant / Guaifenesin, USP 200mg...Expe
 torant

Pkg Size: Exp Date:
 Lot#: Lot#: Batch#: Ins:
 Mfg: Major Pharm.; Livonia, MI
 Prod#: Prod#:

Warning
SEE NEW DOSING. 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. See bottle for complete list of drug information. Non-Drowsy, Raspberry Flavor. Store at 20-25°C (68-77°F). Do not refrigerate.



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed

Robafen® DM Cough & Chest Congestion
 Qty: Ins:
 Lot#: Bat#:


Prod# (NDC):
 Robafen® DM Cough & Chest Congestion
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):

Robafen® DM Cough & Chest Congestion
 Qty:
 Insurance NDC:
 Lot#: Bat#:

Robafen® DM Cough & Chest Congestion
 Qty: Ins:
 Lot#: Bat#:
 Prod# (NDC):


Directions English

Take ___ teaspoonful(s)
) every ___ hours.



Instrucciones Espanol:

Toma ___ cucharrita(s)
) cada ___ horas



Log

Chart

Billing

Patient

ROBAFEN DM			
dextromethorphan hydrobromide, guaifenesin solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-8268(NDC:0904-7223)
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 20 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg in 20 mL	
Inactive Ingredients			
Ingredient Name	Strength		
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)			
FD&C RED NO. 40 (UNII: WZB9127XOA)			
GLYCERIN (UNII: PDC6A3C0OX)			

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	Score	
Shape		Size	
Flavor	FRUIT	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-8268-1	1 in 1 CARTON	09/23/2022	
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	09/23/2022	

Labeler - Preferred Pharmaceuticals Inc. (791119022)

Registrant - Preferred Pharmaceuticals Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals Inc.		791119022	RELABEL(68788-8268)

Revised: 9/2023

Preferred Pharmaceuticals Inc.