

ROBAFEN- dextromethorphan hbr, guaifenesin solution
Preferred Pharmaceuticals, Inc.

Major Pharmaceuticals Robafen® 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

- each 10 mL contains: sodium 6 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, FD&C red no. 40, flavor, glycerin, high fructose corn syrup, menthol, propylene glycol, purified water, sodium benzoate, sodium citrate, sucralose

Questions or comments?

1-800-616-2471

Principal Display Panel

ROBAFEN®

DM COUGH & CHEST CONGESTION

COUGH SUPPRESSANT (Dextromethorphan HBr)

EXPECTORANT (Guaifenesin)

PEAK COLD

Relieves:

Cough



Mucus

Non-Drowsy

COMPARE TO the active ingredients of ROBITUSSIN® COUGH + CHEST CONGESTION DM

NDC 68788-7556-1

Relabeled by Preferred Pharmaceuticals, Inc.

<p>Robafen® DM Generic for Robitussin DM In each teaspoonful (10mL): Dextromethorphan HBr 20mg...Cough Suppressant / Guaifenesin, USP 200mg...Expe ctorant</p> <p>Pkg Size: Exp Date: Lot#: Batch#: Ins: Mfg: Major Pharm.; Livonia, MI Prod#:</p> <p>Warning 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 (muc us), cough that lasts or is chronic such as occurs with smoking asthma, chronic bronchitis, or emphysema. If pregnant or breast feeding, ask a health professional before use. Keep out of the reach of children. Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or hives that lasts. Non-Drowsy. Store at 20-25°C (68-77°F). Do not refrigerate.</p>	 <p>Directions English Take _____ teaspoonful(s)) every _____ hours.</p>	 <p>Instrucciones Español: Toma _____ cucharita(s)) cada _____ horas</p>	<p>CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed</p> <p>Robafen® DM Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Robafen® DM Qty: Ins: Lot#: Bat#: Prod# (NDC):</p> <p>Robafen® DM Qty: Insurance NDC: Lot#: Bat#:</p> <p>Robafen® DM Qty: Ins: Lot#: Bat#: Prod# (NDC):</p>
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ROBAFEN

dextromethorphan hbr, guaifenesin solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7556(NDC:0904-6464)
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
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
HIGH FRUCTOSE CORN SYRUP (UNII: XY6UN3QB6S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	

MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)				
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)				
SUCRALOSE (UNII: 96K6UQ3ZD4)				
Product Characteristics				
Color	RED (clear)		Score	
Shape			Size	
Flavor	CHERRY (Fruity)		Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68788-7556-1	1 in 1 CARTON	12/27/2019	
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 Drug	part341		03/15/1991	

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment			
Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	REPACK(68788-7556)