ROBAFEN DM COUGH- dextromethorphan hbr, guaifenesin solution
Major Pharmaceuticals

Major 44-073

Active ingredients (in each 20 mL)

Dextromethorphan HBr 20 mg
Guaifenesin 200 mg

Purpose

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)
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema

Stop use and ask a doctor if

cough persists more than 7 days, tends to recur, or is accompanied by a 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

- **do not take more than directed**
- do not take more than 6 doses in any 24-hour period
- mL = milliliter
- only use the dose cup provided
- 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 8 mg
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

Inactive ingredients

anhydrous citric acid, flavors, glycerin, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sucralose, xanthan gum

Questions or comments?

1-800-426-9391

Principal display panel

MAJOR®

NDC 0904-7441-20
Compare to the active
ingredients in Robitussin®
Sugar-Free Dye-Free
Cough+Chest Congestion DM*

Sugar Free & Dye Free
Robafen® DM
Cough
Dextromethorphan HBr
Guaifenesin
Cough Suppressant
Expectorant

Oral Solution

• Controls Cough
• Relieves Chest Congestion
• Thins & Loosens Mucus

Ages 12 Years and Over

Cool Mint Flavored

4 FL OZ (118 mL)

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

*This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, owner of the registered trademark Robitussin® Sugar-Free Dye-Free Cough+Chest Congestion DM.
50844 ORG062307336

PARENTS:
Learn about teen medicine abuse
www.StopMedicineAbuse.org

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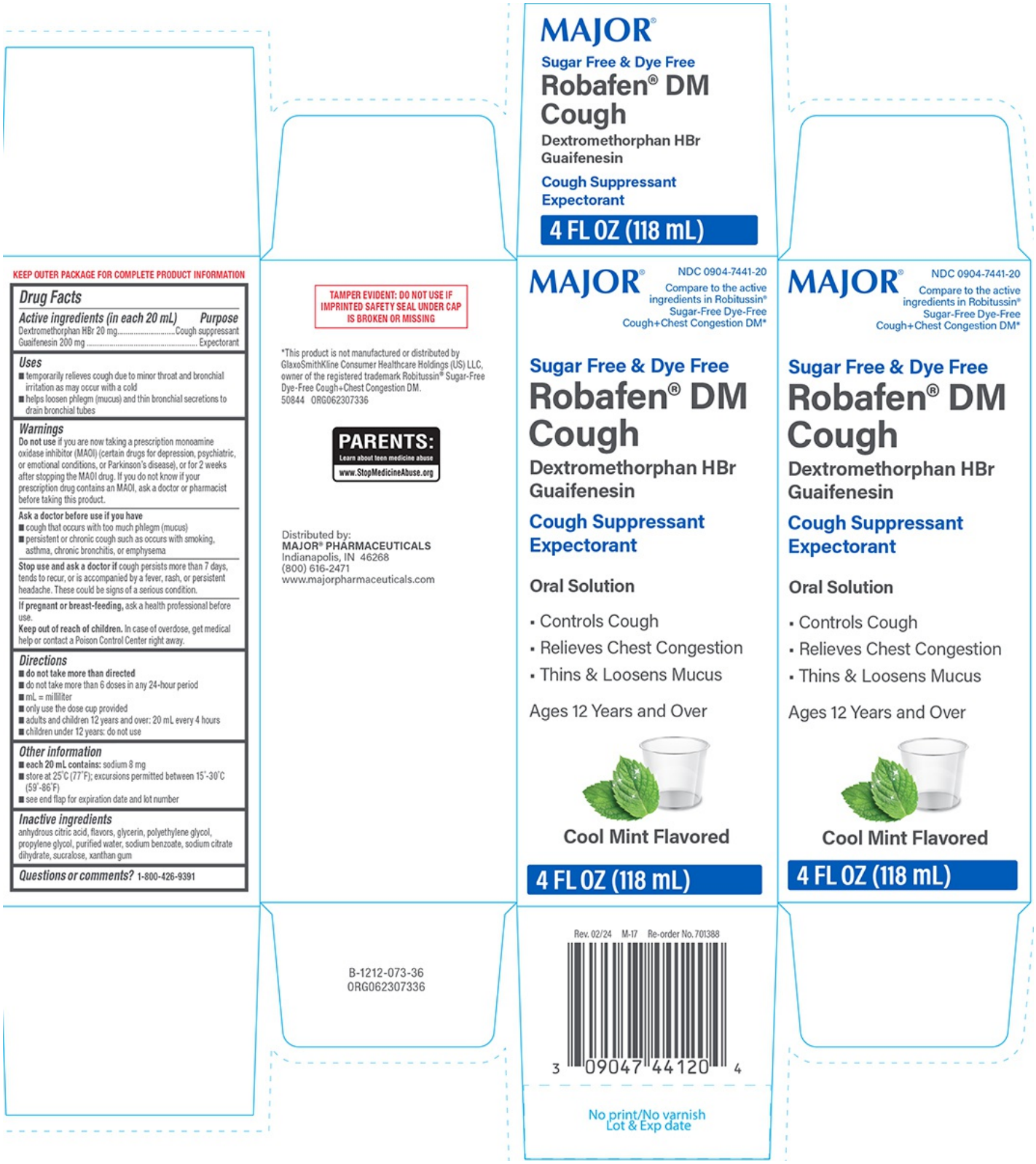
MAJOR® PHARMACEUTICALS
Indianapolis, IN 46268
(800) 616-2471
www.majorpharmaceuticals.com



Major 44-073

ROBAFEN DM COUGH

dextromethorphan hbr, guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0904-7441

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)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	MENTHOL, MINT	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0904-7441-20	1 in 1 CARTON	04/05/2024	
1		118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M012	04/05/2024	

Labeler - Major Pharmaceuticals (191427277)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	manufacture(0904-7441) , pack(0904-7441)