

**ROBITUSSIN MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DM-dextromethorphan hydrobromide and guaifenesin capsule, liquid filled
GlaxoSmithKline Consumer Healthcare Holdings (US) LLC**

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.

Drug Facts

Active ingredients (in each liquid-filled capsule)

Dextromethorphan HBr, USP 10 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 more than 7 days, comes back, or is accompanied by 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 12 capsules in any 24-hour period
- this adult product is not intended for use in children under 12 years of age

age	dose
adults and children 12 years and over	2 capsules every 4 hours
children under 12 years	do not use

Other information

- store at 20-25°C (68-77°F).
- avoid excessive heat above 40°C (104°F).

Inactive ingredients

FD&C Red No. 40, gelatin, glycerin, light mineral oil, pharmaceutical ink, polyethylene glycol, povidone, propylene glycol, purified water, sorbitol sorbitan solution

Questions or comments?

call weekdays from 9 AM to 5 PM EST at **1-800-762-4675**

Made in Canada

For most recent product information, visit www.robitussin.com

Distributed by: Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL

ADULT

Robitussin®

**MAXIMUM
STRENGTH**

**Cough+Chest
Congestion DM**

**DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)**

**DM
MAX**

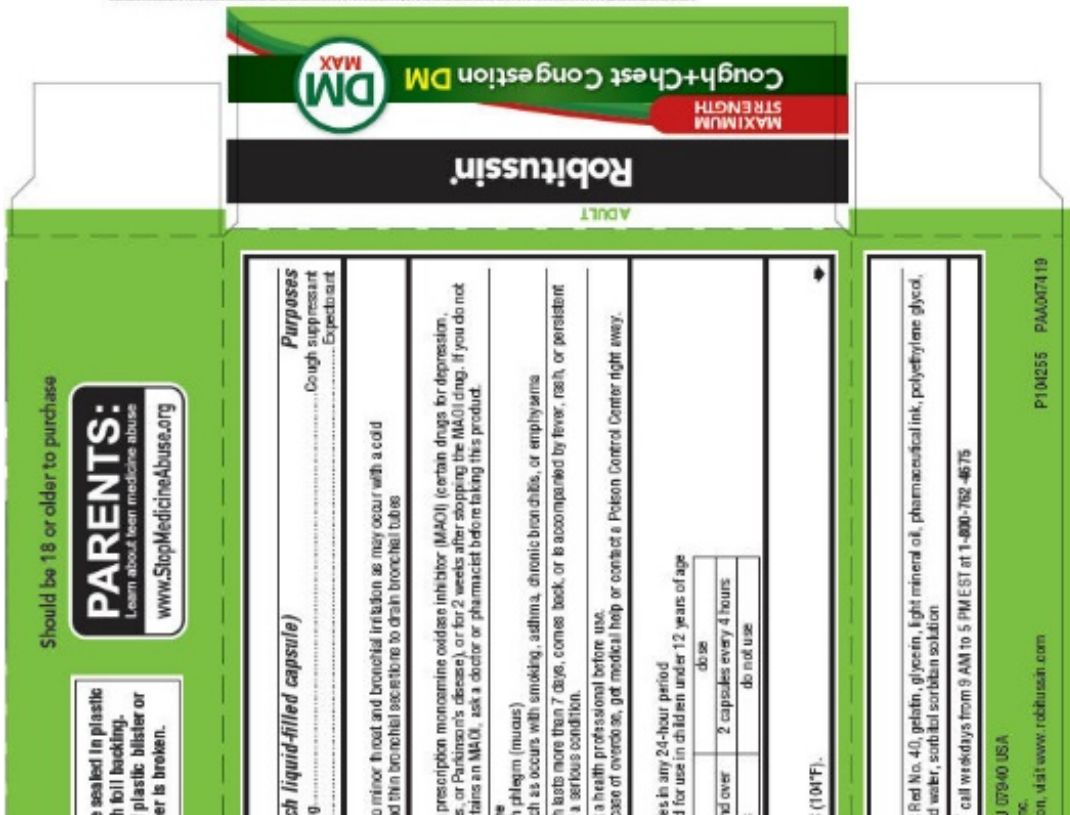
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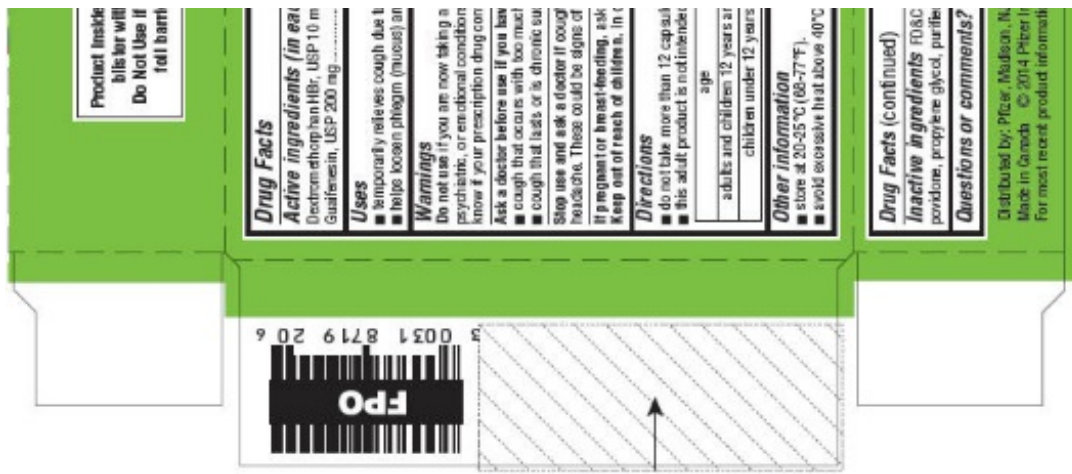
- Cough
- Mucus

Non-Drowsy

For Ages 12 & Over

20
LIQUID-FILLED
CAPSULES





ROBITUSSIN MAXIMUM STRENGTH COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0031-8719
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	200 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	RED (clear red)	Score	no score
Shape	OVAL (oblong)	Size	16mm
Flavor		Imprint Code	R

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8719-10	5 in 1 CARTON	05/02/2016	
1		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0031-8719-20	10 in 1 CARTON	05/23/2013	
2		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0031-8719-31	15 in 1 CARTON	05/23/2013	12/31/2018
3		2 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0031-8719-70	500 in 1 BOX	05/23/2013	12/31/2018
4		2 in 1 POUCH; 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	05/23/2013	

Labeler - GlaxoSmithKline Consumer Healthcare Holdings (US) LLC (079944263)

Revised: 1/2022

GlaxoSmithKline Consumer Healthcare Holdings (US) LLC