CHILDRENS ROBITUSSIN COUGH AND CHEST CONGESTION DM- dextromethorphan hydrobromide, guaifenesin liquid
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 5 ml)

Dextromethorphan HBr, USP 5 mg

Guaifenesin, USP 100 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

- measure only with dosing cup provided
- keep dosing cup with product
- ml = milliliter
- do not take more than 6 doses in any 24-hour period

age	**dose**

children under 4 years	do not use
children 4 to under 6 years	5 ml every 4 hours
children 6 to under 12 years	10 ml every 4 hours
adults and children 12 years and over	20 ml every 4 hours

Other information

- **each 5 ml contains:** sodium 3 mg
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, artificial flavor, FD&C blue no. 1, FD&C red no. 40, glycerin, natural flavor, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose

Questions or comments?

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

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

Distributed by:
Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL

NEW
Dosing
Information

Children's
Robitussin®
NOW FOR AGES 4 & OVER

Cough & Chest
Congestion

DM

DEXTROMETHORPHAN HBr
(Cough Suppressant)
GUAIFENESIN (Expectorant)

Relieves:

 Chest Congestion/Mucus
 Cough

Non-Drowsy

grape
flavor

4 FL OZ
(118 ml)

CHILDRENS ROBITUSSIN COUGH AND CHEST CONGESTION DM

dextromethorphan hydrobromide, guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8715
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
DEXTROMETHORPHAN HYDROBROMIDE (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL
		100 mg

GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL, (R)- (UNII: 602HN5L69H)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color	PURPLE (purple)	**Score**	
Shape		**Size**	
Flavor	GRAPE (grape)	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0031-8715-10	1 in 1 CARTON	07/01/2014	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	07/01/2014	

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

Revised: 10/2020 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC