ROBITUSSIN COUGH PLUS CHEST CONGESTION DM- dextromethorphan hydrobromide and guaifenesin solution
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 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 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 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 20 mg**
- store at 20-25°C (68-77°F). Do not refrigerate.

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, FD&C blue no. 1, FD&C red no. 40, glycerin, liquid glucose, menthol, natural and artificial flavors, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium gluconate, sucralose, triacetin, xanthan gum

Questions or comments?

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

Distributed by:
Pfizer, Madison, NJ 07940 USA

PRINCIPAL DISPLAY PANEL - 237 ml Bottle Carton

ADULT
See
New
Dosing

Robitussin®

Cough+Chest
Congestion DM

DEXTROMETHORPHAN HBr (Cough Suppressant)
GUAIFENESIN (Expectorant)

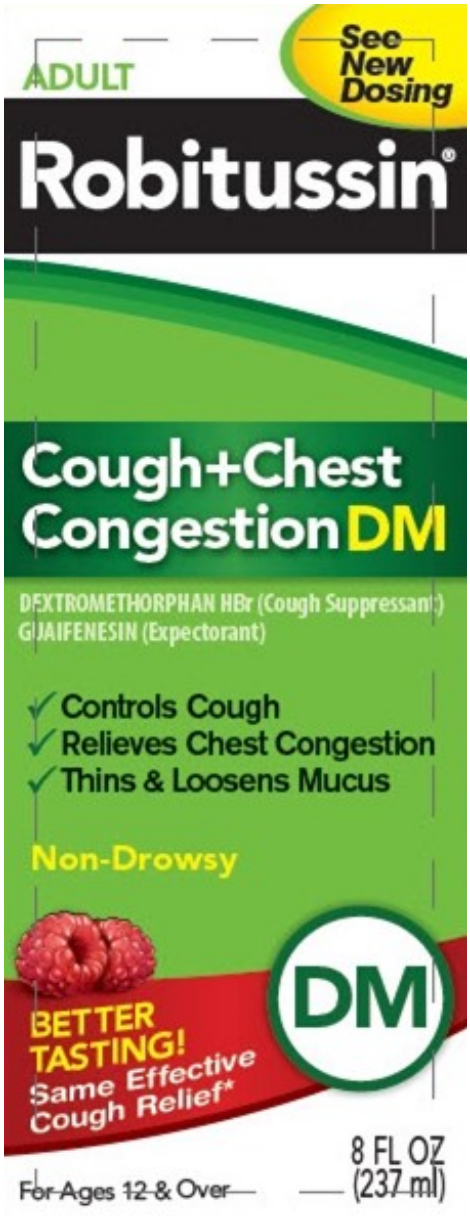
- Controls Cough
- Relieves Chest Congestion
- Thins & Loosens Mucus

Non-Drowsy

BETTER
TASTING!
Same Effective

Cough Relief*
DM

For Ages 12 & Over
8 FL OZ
(237 ml)



ROBITUSSIN COUGH PLUS CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8757
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)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GLYCERIN (UNII: PDC6A3C0OX)	
DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ35W2)	
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SODIUM GLUCONATE (UNII: R6Q3791S76)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	RED	**Score**	
Shape		**Size**	
Flavor	RASPBERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0031-8757-12	1 in 1 CARTON	06/01/2018	
1		118 mL in 1 BOTTLE; Type 1: Convenience Kit of Co-Package		
2	NDC:0031-8757-18	1 in 1 CARTON	06/01/2018	
2		237 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	06/01/2018	

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

Establishment

Name	Address	ID/FEI	Business Operations
PF Consumer Healthcare Canada ULC		203812479	ANALYSIS(0031-8757) , LABEL(0031-8757) , MANUFACTURE(0031-8757) , PACK(0031-8757)

Revised: 1/2023 GlaxoSmithKline Consumer Healthcare Holdings (US) LLC