CHILDRENS ROBITUSSIN COUGH AND CHEST CONGESTION DM-
dextromethorphan hydrobromide and guaifenesin liquid
Haleon US Holdings LLC

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

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 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, natural and artificial flavors, polyethylene glycol, propylene glycol, purified water, sodium benzoate, sodium citrate, sodium gluconate, sucralose, 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 - 118 ml Bottle Label

Children's
Robitussin®

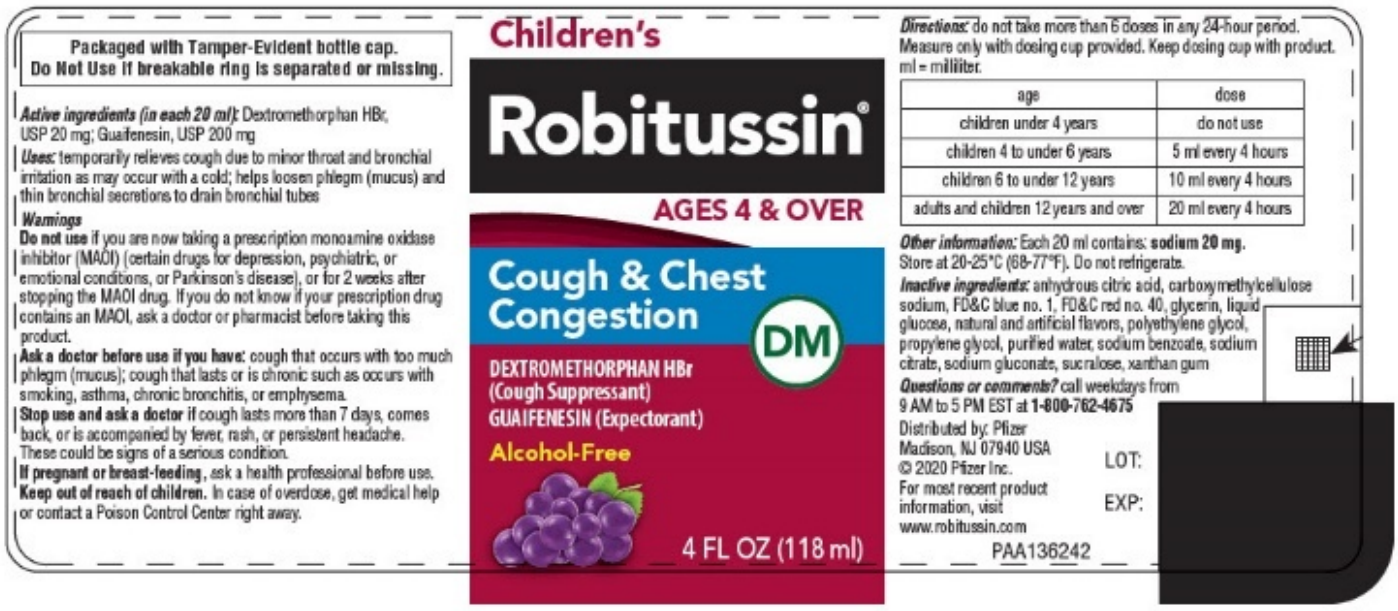
AGES 4 & OVER

Cough & Chest
Congestion
DM

DEXTROMETHORPHAN HBr
(Cough Suppressant)
GUAIFENESIN (Expectorant)

Alcohol-Free

4 FL OZ (118 ml)



PRINCIPAL DISPLAY PANEL - 118 ml Bottle Carton

Children's
Robitussin®

FOR AGES 4 & OVER

Cough & Chest
Congestion
DM

DEXTROMETHORPHAN HBr
(Cough Suppressant)
GUAIFENESIN (Expectorant)

Relieves:

1. Chest Congestion/Mucus
2. Cough

Non-Drowsy

BETTER
TASTING!*
Great Grape Taste

grape flavor

4 FL OZ
(118 ml)

CHILDRENS ROBITUSSIN COUGH AND CHEST CONGESTION DM

dextromethorphan hydrobromide and guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0031-8702
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)	
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)	
XANTHAN GUM (UNII: TTV12P4NEE)	

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:0031-8702-13	1 in 1 CARTON	05/12/2020	
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	M012	05/12/2020	

Labeler - Haleon US Holdings LLC (079944263)

Establishment

Name	Address	ID/FEI	Business Operations
Pf Soins De Santé			ANALYSIS(0031-8702) , LABEL(0031-8702) , MANUFACTURE(0031-8702)

Pf Soins De Sante Sri		203812479	ANALYSIS(0031-8702) , LABEL(0031-8702) , MANUFACTURE(0031-8702) , PACK(0031-8702)