

**DRX CHOICE CHILDREN DAYTIME COUGH AND CHEST CONGESTION-
dextromethorphan hbr and guaifenesin liquid
RARITAN PHARMACEUTICALS**

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.

DRx Choice Children's daytime Cough & Chest Congestion Grape Flavor

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 child's 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 at 1-800-222-1222.

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 older	20 mL every 4 hours

Other information

- each 20 ml contains: **sodium 10 mg**
- store at room temperature. Do not refrigerate.

Inactive ingredients

anhydrous citric acid, carboxymethylcellulose sodium, edetate disodium, glycerin, flavor, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol solution, sucralose, xanthan gum.

Questions or Comments

1-866-467-2748

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 4 FL OZ (118 mL Bottle)

Compare to the active ingredients in **Children's Robitussin® Cough & Chest Congestion DM***

NDC 68163-747-04

DRx Choice®

Children's daytimecough& chestcongestion
Dextromethorphan HBr (Cough Suppressant)
Guaifenesin (Expectorant)

Relieves: Chest congestion, mucus & cough

Sugar Free

Dye Free

No Added Alcohol

For Ages 4 & Over

Grape Flavor

Naturally & Artificially Flavored

4 FL OZ (118 mL)

TAMPER-EVIDENT: DO NOT USE IF PRINTED INNER SEAL UNDER CAP IS TORN OR MISSING

IMPORTANT: KEEP THIS CARTON FOR FUTURE REFERENCE ON FULL LABELING

*This product is not manufactured or distributed by Pfizer, owner of the registered trademarks Children's Robitussin® Cough & Chest Congestion DM.

Manufactured by:

Raritan Pharmaceuticals

8 Joanna Court,

East Brunswick,

NJ, 08816



DRX CHOICE CHILDREN DAYTIME COUGH AND CHEST CONGESTION

dextromethorphan hbr and guaifenesin liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68163-747
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)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	PURPLE	Score	
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68163-747-04	1 in 1 CARTON	04/24/2023	
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 final	part341	04/24/2023	

Labeler - RARITAN PHARMACEUTICALS (127602287)

