# PEDIACARE CHILDRENS COUGH AND CONGESTION GRAPE- dextromethorphan hydrobromide and guaifenesin syrup RANDOB LABS,LTD. DBA CROSSINGWELL CONSUMER HEALTH

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.

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# Pediacare® Children's Cough and Congestion Grape

## **Drug Facts**

Active ingredients (in each 5 mL)	Purposes
Dextromethorphan HBr, USP 5 mg	Cough suppressant
Guaifenesin, USP 100 mg	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 persistant 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
crilidren o to dilder 12 years	hours
adults and children 12 years	20 mL every 4
and over	hours

#### Other information

- store at 20-25°C (68-77°F)
- do not refrigerate
- alcohol-free

#### **Inactive ingredients**

acesulfame potassium, citric acid anhydrous, glycerin, flavor, menthol, polyethylene glycol, povidone, propylene glycol, purified water, sodium benzoate, sodium saccharin

Distributed by CrossingWell Consumer Health PO Box 440 Cornwall, NY 12518

#### PRINCIPAL DISPLAY PANEL - 118 mL Bottle Carton

Fast Acting

Pedia

Care®

100% dedicated

to kids™

4 Years & Up

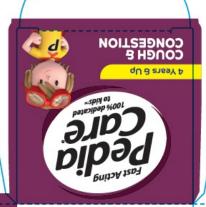
COUGH &

CONGESTION

#### Relieves:

- Congestion & Mucus
- Cough

Dextromethorphan HBr, USP (5 mg per 5 mL) Guaifenesin, USP (100 mg per 5 mL) Non-Drowsy Grape Flavor 4 FL OZ (118 mL)





4 Years & Up

#### COUGH & CONGESTION

#### Relieves:

 Congestion & Mucus · Cough

Dextromethorphan HBr, USP (5 mg per 5 mL) Guaifenesin, USP (100 mg per 5 mL)

Non-Drowsy



Grape Havor

4 FL OZ (118 mL)

100% dedicated to kids™

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#### Drug Facts (continued)

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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

- store at 20-25°C (68-77°F)
- do not refrigerate
- alcohol-free

#### Inactive ingredients

acesulfame potassium, citric acid anhydrous, glycerin flavor, menthol, polyethylene glycol, povidone, propylene glycol, purified water, sodium benzoate, sodium saccharin



CROSSINGWELL consumer health

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Lot# Exp

# PEDIACARE CHILDRENS COUGH AND CONGESTION GRAPE

dextromethorphan hydrobromide and guaifenesin syrup

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:52412-992
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	5 mg in 5 mL	
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	100 mg in 5 mL	

Inactive Ingredients		
Ingredient Name	Strength	
ACESULFAME POTASSIUM (UNII: 230V73Q5G9)		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)		
GLYCERIN (UNII: PDC6A3C0OX)		
MENTHOL, UNSPECIFIED FORM (UNII: L7T10EIP3A)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
WATER (UNII: 059QF0KO0R)		
SODIUM BENZOATE (UNII: OJ245FE5EU)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		

Product Characteristics			
Color PURPLE Score			
Shape		Size	
Flavor	GRAPE	Imprint Code	
Contains			

Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date		
NDC:52412-992-	1 in 1 CARTON	01/03/2023			
1	118 mL in 1 BOTTLE; Type 0: Not a Combination Product				

Marketing Information				
Marketing	Application Number or Monograph	Marketing Start	<b>Marketing End</b>	

Category	Citation	Date	Date
OTC monograph final	part341	01/03/2023	

# Labeler - RANDOB LABS,LTD. DBA CROSSINGWELL CONSUMER HEALTH (061995007)

Revised: 12/2022 RANDOB LABS,LTD. DBA CROSSINGWELL CONSUMER HEALTH