

**PEDIACARE CHILDRENS COUGH AND COLD GRAPE- brompheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride 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 Cold Grape**

**Drug Facts**

<b>Active ingredients (in each 10 ml)</b>	<b>Purposes</b>
Brompheniramine maleate, USP 2 mg	Antihistamine
Dextromethorphan HBr, USP 10 mg	Cough Suppressant
Phenylephrine HCl, USP 5 mg	Nasal decongestant

**Uses**

- temporarily relieves cough due to minor throat and bronchial irritation occurring with a cold, and nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relieves these symptoms due to hay fever (allergic rhinitis):
  - runny nose
  - sneezing
  - itchy, watery eyes
  - itching of the nose or throat
- temporarily restores freer breathing through the nose

**Warnings**

**Do not use**

- to sedate a child or to make a child sleepy
- 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**

- heart disease
- high blood pressure
- thyroid disease

- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- a cough that occurs with too much phlegm (mucus)
- a breathing problem or persistent or chronic cough that lasts such as occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor or pharmacist before use if you are**

- taking any other oral nasal decongestant or stimulant
- taking sedatives or tranquilizers

**When using this product**

- **do not use more than directed**
- may cause marked drowsiness
- avoid alcoholic beverages
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

**Stop use and ask a doctor if**

- you get nervous, dizzy, or sleepless
- symptoms do not get better within 7 days or are accompanied by fever
- 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 dosage cup provided
- keep dosing cup with product
- mL = milliliter

<b>age</b>	<b>dose</b>
adults and children 12 years and over	20 mL every 4 hours
children 6 to under 12 years	10 mL every 4 hours
children under 6 years	do not use

**Other information**

- store at 20-25°C (68-77°F)

## **Inactive ingredients**

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

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™

6 Years & Up

**COUGH & COLD**

Relieves:

- Stuffy, Runny Nose
- Itchy, Watery Eyes
- Sneezing
- Cough

Brompheniramine maleate - Antihistamine  
(2 mg per 10 mL)

Phenylephrine HCl - Nasal decongestant  
(5 mg per 10 mL)

Dextromethorphan HBr - Cough suppressant  
(10 mg per 10 mL)

Alcohol Free

Grape Flavor

4 FL OZ (118 mL)



**Fast Acting**  
**PediaCare**  
 100% dedicated to kids™

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**TAMPER EVIDENT:** Do not use if the safety seal under the cap is broken or missing.

**Drug Facts (continued)**

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**CROSSINGWELL**  
 consumer health

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

0 30103 09200 8

Lot #

Exp

# PEDIACARE CHILDRENS COUGH AND COLD GRAPE

brompheniramine maleate, dextromethorphan hydrobromide, and phenylephrine hydrochloride syrup

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52412-920
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>BROMPHENIRAMINE MALEATE</b> (UNII: IXA7C9ZN03) (BROMPHENIRAMINE - UNII:H57G17P2FN)	BROMPHENIRAMINE MALEATE	2 mg in 10 mL
<b>DEXTROMETHORPHAN HYDROBROMIDE</b> (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS)	DEXTROMETHORPHAN HYDROBROMIDE	10 mg in 10 mL
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg in 10 mL

## Inactive Ingredients

Ingredient Name	Strength
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>SODIUM CITRATE, UNSPECIFIED FORM</b> (UNII: 1Q73Q2JULR)	
<b>SORBITOL</b> (UNII: 506T60A25R)	
<b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)	

## Product Characteristics

<b>Color</b>	PURPLE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	GRAPE	<b>Imprint Code</b>	
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52412-920-01	1 in 1 CARTON	01/03/2023	
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	01/03/2023	

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

Revised: 12/2022

RANDOB LABS,LTD. DBA CROSSINGWELL CONSUMER HEALTH