

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.

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 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

- 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)



COUGH & CONGESTION

4 Years & Up

Fast Acting
PediaCare
100% dedicated to kids™

Fast Acting
PediaCare
100% dedicated to kids™

Fast Acting
PediaCare
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 Flavor

4 FL OZ (118 mL)

Drug Facts

Active ingredients (in each 5 mL) *Purposes*
Dextromethorphan HBr,
USP 5 mgCough suppressant
Guaifenesin, USP 100 mgExpectorant

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=milli liter

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

Drug Facts (continued)

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
■ 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

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



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
DEXTROMETHORPHAN HYDROBROMIDE (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: 23OV73Q5G9)	
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
1	NDC:52412-992-01	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	Marketing End
-----------	---------------------------------	-----------------	---------------

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