COLD-EEZE CHILDRENS DAYTIME COUGH AND CHEST CONGESTION RELIEF-
dextromethorphan hydrobromide and guaifenesin liquid
ProPhase Labs, Inc.

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.

Cold-EEZE®
Children's Daytime Cough & Chest Congestion Relief

Drug Facts

Active Ingredients (in each 5 mL)	*Purpose*
Dextromethorphan HBr 5 mg	Cough suppressant
Guaifenesin 100 mg	Expectorant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves:
  - cough due to minor throat and bronchial irritation as may occur with the common cold or inhaled irritants
  - the intensity of coughing
  - the impulse to cough to help your child get to sleep

Warnings

Do not use in a child who is 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 giving this product. Avoid foods or beverages that contain caffeine.

Ask a doctor before use if the child has

- cough that occurs with too much phlegm (mucus)
- persistent or chronic cough such as occurs with asthma

Stop use and ask a doctor if cough lasts more than 7 days, comes back, or occurs with fever, rash, or persistent headache. These could be signs of a serious illness.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions

- measure with dosing cup provided
- dose as follows or as directed by a doctor
- mL = milliliter

Age	Dose
children 6 years to under 12 years	5 mL (1 tsp) - 10 mL (2 tsp) orally every 4 hours, not to exceed 6 doses in 24 hours

children 4 years to under 6 years	2.5 mL (1/2 tsp) - 5 mL (1 tsp) orally every 4 hours, not to exceed 6 doses in 24 hours
children under 4 years	do not use

Other information

- each 5 mL teaspoonful contains: **sodium 3 mg**
- tamper evident: do not use if foil seal under bottle cap is open or missing
- store between 20-25°C (68-77°F)
- do not refrigerate
- dosing cup provided

Inactive ingredients

citric acid anhydrous, flavors, disodium edetate, glycerin, propyl gallate, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Questions?

1-800-505-2653
(M-F: 9AM-5PM EST)
You may also report side effects to this phone number

Distributed by:
ProPhase Labs, Inc.
PO Box 1349
Doylestown, PA 18901

PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label

Children's
Cold-EEZE®
Daytime
Cough & Chest
Congestion Relief

Guaifenesin 100 mg • Expectorant

Dextromethorphan HBr 5 mg • Cough Suppressant

MULTI-SYMPTOM

Relief of:

- **Cough**
- **Breaks Up Mucus**
- **Chest Congestion**

Alcohol Free
Dye Free

Cherry Flavor

For Ages 4+
6 fl oz (180 mL)

3001000215--47009

NDC 61941-0400-1

Children's

Cold-EEZE®

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- do not refrigerate
- dosage cup provided

Please visit our website at www.coldeeze.com
Questions or Comments:
Call: 1-800-505-2653
(M-F: 9AM-5PM EST)
Manufactured for and Distributed by:
ProPhase Labs, Inc.
PO Box 1349
Doylestown, PA 18901

info@ProPhaseLabs.com

PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

Tamper evident: do not use if foil seal under bottle cap is open or missing.

Dose every 4 hours.

3001000216-470010

LOT:

EXP:

COLD-EEZE CHILDRENS DAYTIME COUGH AND CHEST CONGESTION

RELIEF

dextromethorphan hydrobromide and guaifenesin liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61941-0400
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 5 mL
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	400 mg in 5 mL

Inactive Ingredients	
Ingredient Name	**Strength**
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Edetate Disodium (UNII: 7FLD91C86K)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Water (UNII: 059QF0KO0R)	
Propyl Gallate (UNII: 8D4SNN7V92)	
Sodium Benzoate (UNII: OJ245FE5EU)	
Sodium Citrate, Unspecified Form (UNII: 1Q73Q2JULR)	
Sorbitol (UNII: 506T60A25R)	
Sucralose (UNII: 96K6UQ3ZD4)	
Xanthan Gum (UNII: TTV12P4NEE)	

Product Characteristics			
Color	WHITE (Clear/White)	**Score**	
Shape		**Size**	
Flavor	CHERRY	**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:61941-0400-1	180 mL in 1 BOTTLE, UNIT-DOSE; 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	01/01/2016	

Labeler - ProPhase Labs, Inc. (620557298)

Establishment

Name	Address	ID/FEI	Business Operations
ProPhase Labs, Inc.		620557298	LABEL(61941-0400) , ANALYSIS(61941-0400) , REPACK(61941-0400)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE(61941-0400) , PACK(61941-0400) , REPACK(61941-0400)

Revised: 1/2016 ProPhase Labs, Inc.