COLD-EEZE CHILDRENS NIGHTTIME COLD AND COUGH RELIEF- acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride 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 Nighttime Cold & Cough Relief

Drug Facts

Active Ingredients (in each 10 mL)	*Purpose*
Acetaminophen 325 mg	**Pain reliever/fever reducer**
Diphenhydramine HCl 12.5mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporary relief for these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose
  - sneezing
  - cough
- controls cough to help your child get to sleep
- temporarily reduces fever

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert

Acetaminophen may cause severe skin reactions.
Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Avoid foods or beverages that contain caffeine.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- to make a child sleepy
- with any other drug containing diphenhydramine, even one used on the skin
- 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.

Ask a doctor before use if your child has

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- a breathing problem such as chronic bronchitis
- persistent or chronic cough such as occurs with asthma
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if your child is

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse, or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

Keep out of reach of children.

Overdose warning

Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- if needed, repeat dose every 4 hours while symptoms last

- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided
- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

Other information

- each 10 mL contains: **sodium 6 mg**
- store between 20-25°C (68-77°F)
- dosing cup provided
- do not refrigerate
- dosing cup provided
- tamper evident: do not use if foil seal under bottle cap is open or missing

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, 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

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

PRINCIPAL DISPLAY PANEL - 180 mL Bottle Label

Children's
Cold-EEZE®
Nighttime
Cold & Cough

3001000213--47011

NDC 61941-0401-1

Acetaminophen 325 mg • Pain Reliever/Fever Reducer

Diphenhydramine HCl 12.5 mg • Antihistamine/Cough Suppressant

Phenylephrine HCl 5 mg • Nasal Decongestant

MULTI-SYMPTOM

Relief of:

- **Cough**

- **Sore Throat**
- **Fever**
- **Stuffy Nose**

Alcohol Free

Berry Flavor

For Ages 6+
6 fl oz (180 mL)

Children's

Cold-EEZE®

Nighttime

Cold & Cough

Acetaminophen 325 mg • Pain Reliever/Fever Reducer
Diphenhydramine HCl 12.5 mg • Antihistamine/Cough Suppressant
Phenylephrine HCl 5 mg • Nasal Decongestant

MULTI-SYMPTOM

Relief of:

- ☑ Cough
- ☑ Fever
- ☑ Sore Throat
- ☑ Stuffy Nose

Berry Flavor

For Ages 6+

Alcohol Free

6 fl oz (180 mL)

3001000213–47011

NDC 61941-0401-1

Drug Facts

Active Ingredients (in each 10 mL)	Purpose
Acetaminophen 325 mg	Pain reliever/fever reducer
Diphenhydramine HCl 12.5mg	Antihistamine/cough suppressant
Phenylephrine HCl 5 mg	Nasal decongestant

Uses

- temporary relief for these common cold and flu symptoms:
  - minor aches and pains
  - headache
  - sore throat
  - nasal congestion
  - runny nose
  - sneezing
  - cough
- controls cough to help your child get to sleep
- temporarily reduces fever

Warnings

Allergy alert:
Acetaminophen may cause severe skin reactions.
Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.
Avoid foods or beverages that contain caffeine.

Sore throat warning: if sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

- with any other drug containing acetaminophen
- 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.

Ask a doctor before use if your child has

- liver disease
- heart disease
- diabetes
- high blood pressure
- thyroid disease
- glaucoma
- a breathing problem such as
- drug warfarin
- taking sedatives or tranquilizers

When using this product

- **do not use more than directed**
- excitability may occur, especially in children
- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain, nasal congestion, or cough gets worse or lasts more than 5 days
- fever gets worse, or

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes:

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

(prescription or non prescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

- to make a child sleepy
- with any other drug containing diphenhydramine, even one used on the skin

chronic bronchitis

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

Ask a doctor or pharmacist before use if your child is

- taking the blood thinning

lasts more than 3 days

- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with fever, rash, or headache that lasts. These could be signs of a serious condition.

Drug Facts *(continued)*

Keep out of reach of children.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **this product does not contain directions or complete warnings for adult use**
- **do not give more than directed (see Overdose warning)**
- if needed, repeat dose every 4 hours while symptoms last
- do not give more than 5 days unless directed by a doctor
- measure only with dosing cup provided

Drug Facts *(continued)*

- do not use dosing cup with other products
- dose as follows or as directed by a doctor
- mL = milliliter
- children 6 to under 12 years of age: 10 mL in dosing cup provided every 4 hours; do not give more than 5 doses in any 24-hour period
- children under 6 years of age: do not use

Other information

- each 10 mL contains: **sodium 6 mg**
- store between 20-25°C (68-77°F)
- dosing cup provided
- do not refrigerate
- dosing cup provided
- tamper evident: do not use if foil seal under bottle cap is open or missing

Inactive ingredients

anhydrous citric acid, edetate disodium, FD&C Blue #1, FD&C Red #40, flavors, glycerin, propylene glycol, propyl gallate, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose, xanthan gum

Drug Facts *(continued)*

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

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

© 2015

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.

0 91108 20575 6

3001000214-470012

LOT:

EXP:

COLD-EEZE CHILDRENS NIGHTTIME COLD AND COUGH RELIEF

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61941-0401
Route of Administration	ORAL		

Active Ingredient/Active Moiety		

Ingredient Name	Basis of Strength	Strength
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	325 mg in 10 mL
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	12.5 mg in 10 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	5 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
Anhydrous Citric Acid (UNII: XF417D3PSL)	
Edetate Disodium (UNII: 7FLD91C86K)	
FD&C Blue NO. 1 (UNII: H3R47K3TBD)	
FD&C Red NO. 40 (UNII: WZB9127XOA)	
Glycerin (UNII: PDC6A3C0OX)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Propyl Gallate (UNII: 8D4SNN7V92)	
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	BLUE	**Score**	
Shape		**Size**	
Flavor	BERRY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-0401-1	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(61941-0401) , ANALYSIS(61941-0401) , REPACK(61941-0401)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE(61941-0401) , PACK(61941-0401) , REPACK(61941-0401)