COLD-EEZE NIGHTTIME COLD AND FLU- 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®
Nighttime Cold & Flu

Drug Facts

Active Ingredients (in each 20 mL)	*Purpose*
Acetaminophen 650 mg	**Pain reliever/fever reducer**
Diphenhydramine HCl 25mg	Antihistamine/cough suppressant
Phenylephrine HCl 10 mg	Nasal decongestant

Uses

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

Warnings

Liver warning

This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks daily while using this product

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.

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.
- with any other drug containing diphenhydramine, even one used on the skin
- if you are not 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.
- for children under 12 years of age

Ask a doctor before use if you have

- liver disease
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- glaucoma
- breathing problems such as emphysema or chronic bronchitis
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis or emphysema
- cough that occurs with too much phlegm (mucus)

Ask a doctor or pharmacist before use if

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

When using this product

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

Stop use and ask a doctor if

- nervousness, dizziness or sleeplessness occur
- pain, nasal congestion or cough gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- cough comes back, or occurs with 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.

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

- **do not take more than directed (see Overdose warning)**
- 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
- **Adults and children 12 years and older:** 20 mL orally every 4 hours, not to exceed 6 doses in 24 hours.
- **Children under 12 years of age:** Do not use unless directed by a doctor

Other information

- each 20 mL contains: **sodium 12 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

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

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

PRINCIPAL DISPLAY PANEL - 266 mL Bottle Label

MAXIMUM STRENGTH

Cold-EEZE®

NIGHTTIME
Cold & Flu

Acetaminophen 650 mg • Pain Reliever/Fever Reducer

Diphenhydramine HCl 25 mg • Antihistamine/Cough Suppressant

Phenylephrine HCl 10 mg • Nasal Decongestant

MULTI-SYMPTOM

Relief of:

- **Headache, Aches, Fever & Sore Throat**
- **Cough**
- **Nasal Congestion**

- **Sneezing and Runny Nose**

For Ages 12+
9 fl oz (266 mL)

3001000209-47007

NDC 61941-0301-1

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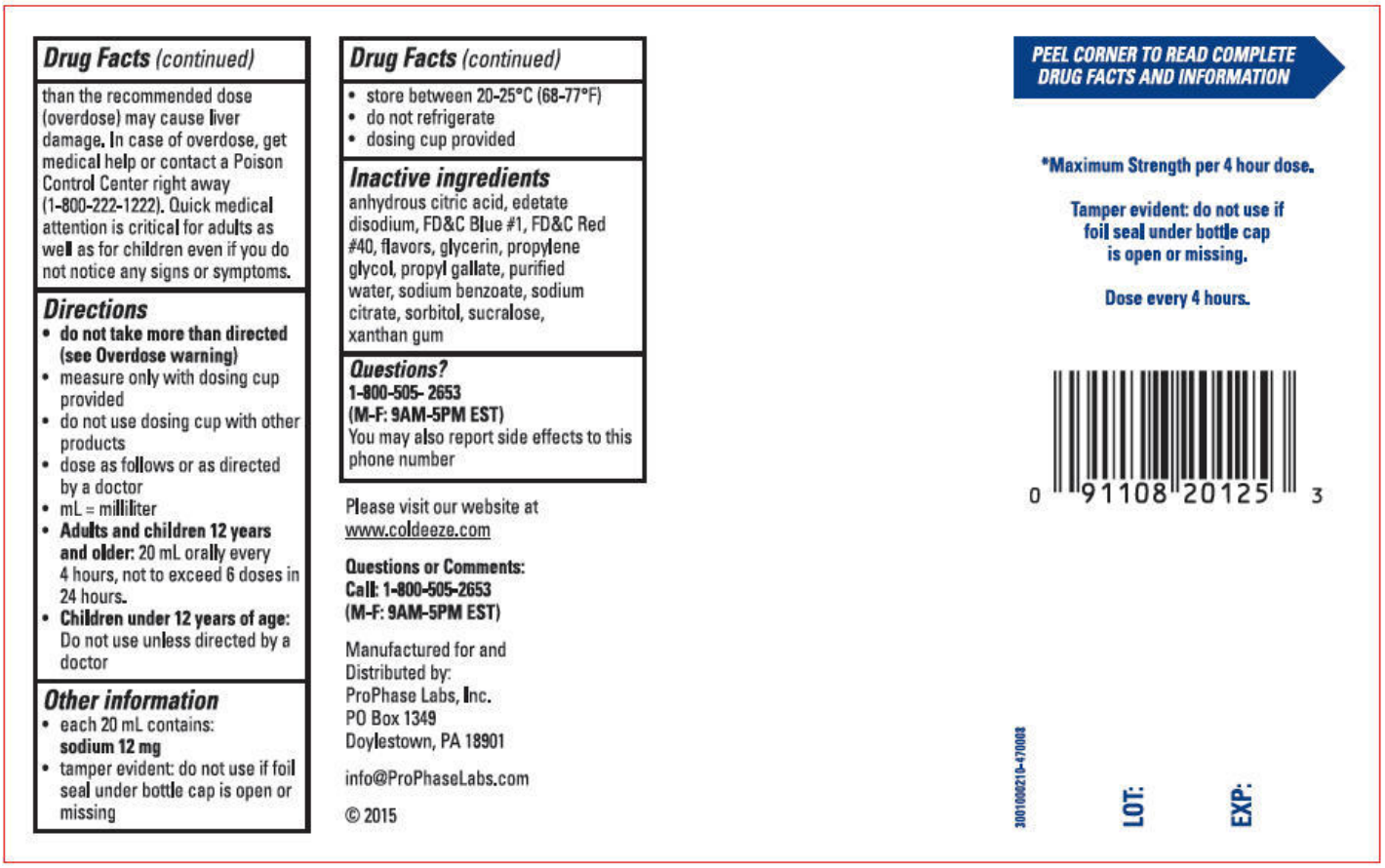
Overdose warning: Taking more



Drug Facts *(continued)*

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.

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Drug Facts *(continued)*

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- do not refrigerate
- dosing cup provided

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

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

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PEEL CORNER TO READ COMPLETE DRUG FACTS AND INFORMATION

*Maximum Strength per 4 hour dose.

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

Dose every 4 hours.

0 91108 20125 3

LOT:

EXP:

COLD-EEZE NIGHTTIME COLD AND FLU

acetaminophen, diphenhydramine hydrochloride, and phenylephrine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61941-0301
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Acetaminophen (UNII: 362O9ITL9D) (Acetaminophen - UNII:362O9ITL9D)	Acetaminophen	650 mg in 20 mL
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	25 mg in 20 mL
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	10 mg in 20 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:61941-0301-1	266 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(61941-0301) , ANALYSIS(61941-0301) , REPACK(61941-0301)

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE(61941-0301) , PACK(61941-0301) , REPACK(61941-0301)

Revised: 1/2016 ProPhase Labs, Inc.