

KIDS-EEZE COUGH AND COLD- dextromethorphan hydrobromide and phenylephrine hydrochloride tablet, orally disintegrating
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.

Kids-EEZE®
Cough
& Cold
Soft Chews
Great Tasting Grape

Drug Facts

<i>Active ingredients (in each soft chew)</i>	<i>Purposes</i>
Dextromethorphan Hydrobromide 5mg	Cough Suppressant
Phenylephrine Hydrochloride 2.5mg	Nasal Decongestant

Uses

Temporarily

- relieves cough and nasal congestion associated with a cold or hay fever
- helps you cough less
- controls the intensity of coughing
- reduces the impulse to cough to help you sleep
- relieves the cough impulses without narcotics
- relieves stuffy nose and sinus congestion and pressure

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

- a persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus)
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- difficulty in urination due to enlargement of the prostate gland

When using this product

- **do not exceed recommended dosage**

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur

- symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash, or persistent headache. These may be symptoms 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

Chew and swallow as directed below

- **Do not take more than 6 doses in 24 hours**

adults and children 12 years and over	4 chews every 4 hours
children 6 years to under 12 years	2 chews every 4 hours
children under 6 years of age	ask a doctor

Other information

- **each soft chew contains 6 mg sodium**
- tamper evident: do not use if inner blister pack is torn or open
- store at controlled room temperature 15-30°C (59-86°F)

Inactive ingredients

ammonium glycyrrhizinate, cellulose acetate, croscarmellose sodium, D&C red # 27 aluminum lake, eudragit E acrylic polymer, FD&C blue #1 aluminum lake, fructose, flavors, hydroxypropylmethylcellulose, lecithin, malic acid, microcrystalline cellulose, sodium chloride, sodium lauryl sulfate, sucralose, sugar, vegetable oil, xylitol

To report serious side effects associated with the use of this product call **1-800-505-COLD (2653)**

PRINCIPAL DISPLAY PANEL - 12 SOFT CHEW PACKAGE

NDC 61941-1003-6

Kids-EEZE®

From The Makers Of

Cold-EEZE®

**Cough
& Cold**

COUGH SUPPRESSANT • DEXTROMETHORPHAN HBr 5mg

NASAL DECONGESTANT • PHENYLEPHRINE HCl 2.5mg

For relief of:

- + Coughs
- + Stuffy Nose
- + Sinus Congestion

Soft Chew

Great Tasting Grape

ARTIFICIALLY FLAVORED

12 SOFT CHEWS

TAMPER EVIDENT: Do Not Use If Inner Seal Is Torn Or Open

Rev 08/2010

Kids-EEZE
From The Makers Of
Cold-EEZE

Cough & Cold

NDC 61941-1003-6

Kids-EEZE
From The Makers Of
Cold-EEZE

**Cough
& Cold**

COUGH SUPPRESSANT • DEXTROMETHORPHAN HBr 5mg
NASAL DECONGESTANT • PHENYLEPHRINE HCl 2.5mg

For relief of:

- + Coughs
- + Stuffy Nose
- + Sinus Congestion



Soft Chew

Great Tasting Grape

ARTIFICIALLY FLAVORED
12 SOFT CHEWS

TAMPER EVIDENT: Do Not Use If Inner Seal Is Torn Or Open

Drug Facts (continued)

Inactive ingredients ammonium glycyrrhizinate, cellulose acetate, croscarmellose sodium, D&C red # 27 aluminum lake, eudragit E acrylic polymer, FD&C blue #1 aluminum lake, fructose, flavors, hydroxypropylmethylcellulose, lecithin, malic acid, microcrystalline cellulose, sodium chloride, sodium lauryl sulfate, sucralose, sugar, vegetable oil, xylitol

To report serious side effects associated with the use of this product call **1-800-505-COLD (2653)**

Manufactured for and distributed by:

ProPhase Labs, Inc.

P.O. Box 1349

Doylstown, PA 18901

E-mail: info@prophaselabs.com

Patent Nos. 6,340,471 and 6,541,025

Kids-EEZE
From The Makers Of
Cold-EEZE

**Cough
& Cold**

Coughs
+
Stuffy Nose
+
Sinus Congestion



Drug Facts

Active ingredients (in each soft chew) Purposes

Dextromethorphan Hydrobromide 5mg.....Cough Suppressant
Phenylephrine Hydrochloride 2.5mg.....Nasal Decongestant

Uses

Temporarily
• relieves cough and nasal congestion associated with a cold or hay fever
• helps you cough less
• controls the intensity of coughing
• reduces the impulse to cough to help you sleep
• relieves the cough impulses without narcotics
• relieves stuffy nose and sinus congestion and pressure

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

• a persistent or chronic cough such as occurs with smoking, asthma, or emphysema, or if cough is accompanied by excessive phlegm (mucus)
• heart disease
• high blood pressure
• thyroid disease
• diabetes
• difficulty in urination due to enlargement of the prostate gland

When using this product

• do not exceed recommended dosage

Stop use and ask a doctor if

• nervousness, dizziness, or sleeplessness occur
• symptoms do not improve within 7 days, tend to recur or are accompanied by fever and rash, or persistent headache. These may be symptoms 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:

Chew and swallow as directed below

• Do not take more than 6 doses in 24 hours

adults and children 12 years and over	4 chews every 4 hours
children 6 years to under 12 years	2 chews every 4 hours
children under 6 years of age	ask a doctor

Other information

• each soft chew contains 6 mg sodium
• tamper evident: do not use if inner blister pack is torn or open
• store at controlled room temperature 15-30°C (59-86°F)



PN 10458-77D1-02

KIDS-EEZE COUGH AND COLD

dextromethorphan hydrobromide and phenylephrine hydrochloride tablet, orally disintegrating

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:61941-1003
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
Phenylephrine Hydrochloride (UNII: 04JA59TNSJ) (Phenylephrine - UNII:1WS297W6MV)	Phenylephrine Hydrochloride	2.5 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CELLULOSE ACETATE (UNII: 3J2P07GVB6)	
FRUCTOSE (UNII: 6YSS42VSEV)	
MALIC ACID (UNII: 817L1N4CKP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XYLITOL (UNII: VCQ006KQ1E)	

Product Characteristics

Color	PURPLE	Score	no score
Shape	OVAL	Size	17mm
Flavor	GRAPE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-1003-1	72 in 1 CASE		
1	NDC:61941-1003-6	12 in 1 PACKAGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/01/2010	

Labeler - ProPhase Labs, Inc. (620557298)

Establishment

Name	Address	ID/FEI	Business Operations
ProPhase Labs, Inc.		620557298	LABEL, ANALYSIS

Establishment

Name	Address	ID/FEI	Business Operations
Pharmaloz Manufacturing, Inc.		067101998	MANUFACTURE, ANALYSIS, PACK, REPACK

Revised: 4/2011

ProPhase Labs, Inc.