KIDS-EEZE CHEST RELIEF- guaifenes in 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® Chest Relief

Drug Facts

Active ingredient (in each soft chew)

Guaifenesin, USP 100 mg

Purpose

Expectorant

Uses

helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive.

Warnings

Ask a doctor before use if you have

- a sodium-restricted diet
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

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 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	2 to 4 chews every 4 hours
children 6 years to under 12 years	1 to 2 chews every 4 hours
children under 6 years of age	ask a doctor

Other information

- each soft chew contains 17 mg sodium
- tamper evident: do not use if inner blister pack is torn or open
- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients

croscarmelose sodium, ethylcellulose, FD&C red #40 lake, ethylene glycol & vinyl alcohol graft copolymer, malic acid, methacrylic copolymer, monoammonium glycyrrhizinate, non fat dry milk, octaglycerol monooleate emulsifier, vegetable oil, polysorbate 80, salt, silicon dioxide, sodium starch glycolate, soy lecithin, strawberry flavors, sucralose, sugar, vanilla flavor

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

PRINCIPAL DISPLAY PANEL - 100 mg Tablet Carton

NDC 61941-1002-6

Kids-EEZE®

From The Makers Of Cold-EEZE[®]

Chest Relief

EXPECTORANT • GUAIFENESIN 100 mg

- Relieves Chest
 Congestion
- + Thins & Loosens Mucus

Soft Chew

Great Tasting Strawberry

ARTIFICIALLY FLAVORED 12 SOFT CHEWS

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





Chest Relief





EXPECTORANT • GUAIFENESIN 100 mg

- + Relieves Chest Congestion
- + Thins & Loosens Mucus







Soft Chew

Great Tasting Strawberry ARTIFICIALLY FLAVORED 12 SOFT CHEWS





actured for and distributed by ProPhase Labs, Inc.
P.O. Box 1349
Doylestown, PA 18901
all: info@prophaselabs.com

Drug Facts

Active ingredient (in each soft chew) Purpose
Guaifenesin, USP 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.

Warnings

Ask a doctor before use if you have

- a sodium-restricted diet persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough that occurs with too much phlegm (mucus)

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 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	2 to 4 chews every 4 hours
children 6 years to under 12 years	1 to 2 chews every 4 hours
children under 6 years of age	ask a doctor

Other information

- · each soft chew contains 17 mg sodium
- tamper evident: do not use if inner blister pack is torn or open
- store at controlled room temperature 20-25°C (68-77°F)

Inactive ingredients croscarmelose sodium, ethylcellulose, FD&C red #40 lake, ethylene glycol & vinyl alcohol graft copolymer, malic acid, methacrylic copolymer, monoammonium glycyrrhizinate, non fat dry milk, octaglycerol monooleate emulsifier, vegetable oil, polysorbate 80, salt, silicon dioxide, sodium starch glycolate, soy



KIDS-EEZE CHEST RELIEF

guaifenesin tablet, orally disintegrating

D	r۸	А	net	Info	rmation	
г	ĽU	ĮΨ		HIHO)	

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:61941-1002

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Guaifenesin (UNII: 495W7451VQ) (Guaifenesin - UNII:495W7451VQ)	Guaifenesin	100 mg

Inactive Ingredients	
Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28 OL 1HH48)	
ETHYLCELLULOSE (4 MPA.S) (UNII: KC5472WRJK)	
ETHYLENE GLYCOL (UNII: FC72KVT52F)	
MALIC ACID (UNII: 817L1N4CKP)	
LECITHIN, SO YBEAN (UNII: 1DI56 QDM62)	
METHACRYLIC ACID - METHYL METHACRYLATE COPOLYMER (1:2) (UNII: 5KY68S2577)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	

Product Characteristics

Color RED Score no score

Shape	OVAL	Size	23mm
Flavor	STRAWBERRY	Imprint Code	
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61941-1002-1	72 in 1 CASE		
1	NDC:61941-1002-6	12 in 1 PACKAGE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	09/01/2008	

Labeler - ProPhase Labs, Inc. (620557298)

Establishment			
Name	Address	ID/FEI	Business Operations
Pro Phase 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.