KIDS-EEZE ALLERGY- diphenhydramine 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®
Allergy
Soft Chews
Great Tasting Grape

Drug Facts

Active ingredient (in each soft chew)

Diphenhydramine Hydrochloride 12.5mg

Purpose

Antihistamine

Uses

For the temporary relief of
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes due to hay fever or other upper respiratory allergies

Warnings

Do not use
- with any other product containing diphenhydramine, even one used on the skin

Ask a doctor before use if you have
- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland

Ask a doctor before use if you are taking sedatives or tranquilizers.

When using this product
- marked drowsiness may occur
- alcohol, sedatives and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages while taking this product
- use caution when driving a motor vehicle or operating machinery
- excitability may occur, especially in children

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 to 6 hours
children 6 years to under 12 years	1 to 2 chews every 4 to 6 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, croscarmellose sodium, D&C red #27 lake, ethylcellulose, FD&C blue #1 lake, fructose, flavors, hydroxypropylcellulose, lecithin, malic acid, microcrystalline cellulose, sodium chloride, 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 - 12.5 mg Package

NDC 61941-1005-6

Kids-EEZE®
From The Makers Of
Cold-EEZE®

Allergy

ANTIHISTAMINE • DIPHENHYDRAMINE HCl 12.5mg
Due to hay fever or upper respiratory allergies

For relief of:

+ Runny Nose
+ Sneezing
+ Itchy Watery Eyes
+ Itchy Throat

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

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Kids-EEZE
From The Makers Of Cold-EEZE

Allergy

Manufactured for and distributed by:
ProPhase Labs, Inc.
P.O. Box 1349
Doylestown, PA 18901
E-mail: info@prophaselabs.com
Patent Nos. 6,340,471 and 6,541,025

MADE IN USA

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Active ingredient *(in each soft chew)* **Purpose**
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PN 10455-77D1-02

KIDS-EEZE ALLERGY

diphenhydramine hydrochloride tablet, orally disintegrating

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:61941-1005
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Diphenhydramine Hydrochloride (UNII: TC2D6JAD40) (Diphenhydramine - UNII:8GTS82S83M)	Diphenhydramine Hydrochloride	12.5 mg

Inactive Ingredients	
Ingredient Name	**Strength**
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
ETHYLCELLULOSE (4 MPA.S) (UNII: KC5472WRJK)	
FRUCTOSE (UNII: 6YSS42VSEV)	
MALIC ACID (UNII: 817L1N4CKP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
XYLITOL (UNII: VCQ006KQ1E)	
HYDROXYPROPYL CELLULOSE (UNII: RFW2ET671P)	

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:61941-1005-1	72 in 1 CASE		
1	NDC:61941-1005-6	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.