ALLERGY RELIEF- diphenhydramine hcl tablet
Kareway Product, 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.

Drug Facts

Active ingredient (in each tablet)

Diphenhydramine HCL 25mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever or other upper respiratory allergies:
- runny nose
- sneezing
- itchy, watery eyes
- itching of the nose or throat
- temporarily relieves these symptoms due to the common cold
- runny nose
- sneezing

Warnings

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

Ask a doctor before use if you have

- glaucoma
- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland

Ask a doctor or pharmacist before use if you are

taking sedatives or tranquilizers

When using this product

- marked drowsiness may occur
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase drowsiness
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose get medical help or contact a Poison Control Center right away.

Directions

- take every 4 to 6 hours
- do not take more than 6 doses in 24 hours

adults and children 12 years of age and over	25 mg to 50 mg (1 to 2 tablets)
children 6 to under 12 years of age	12.5** to 25 mg (1 tablet)
children under 6 years of age	ask a doctor

**12.5 mg dosage strength is not available in this package. Do not attempt to break tablets.

Other information

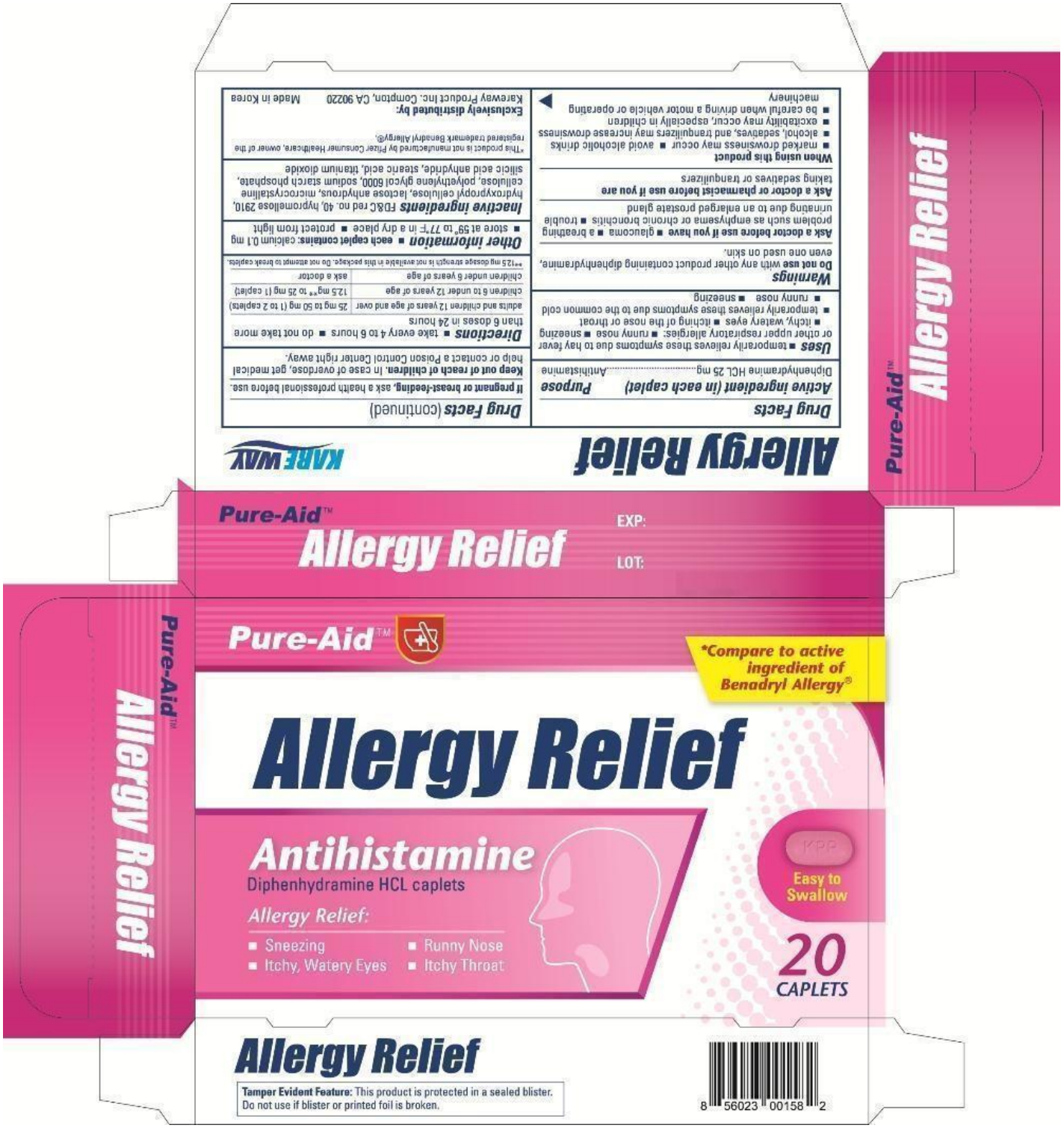
- **each tablet contains:** calcium 0.1mg
- store at 59° to 77°F in a dry place
- protect from light

Inactive ingredients

microcrystalline cellulose, lactose anhydrous, sodium starch glycolate, pregelatinized starch, dibasic calcium phosphate dihydrate, crospovidone, stearic acid, magnesium stearate, hypromellose, polyethyleneglycol, titanium dioxide, ethanol

Package label

Allergy Relief



ALLERGY RELIEF

diphenhydramine hcl tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:67510-0158
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	25 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE WAX (UNII: XOF597Q3KY)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
STARCH, CORN (UNII: O8232NY3SJ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CROSPOVIDONE (UNII: 68401960MK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
ETHANETHIOL (UNII: M439R54A1D)	

Product Characteristics

Color	blue	**Score**	no score
Shape	ROUND	**Size**	9mm
Flavor		**Imprint Code**	BE
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67510-0158-2	2 in 1 BOX		
1		12 in 1 BLISTER PACK		
2	NDC:67510-0158-4	4 in 1 BOX		
2		12 in 1 BLISTER PACK		
3	NDC:67510-0158-0	2 in 1 BOX		
3		10 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	08/18/2011	

Labeler - Kareway Product, Inc. (121840057)

Revised: 2/2013 Kareway Product, Inc.