PREMIER VALUE ALLERGY - diphenhydramine hydrochloride cream
TAI GUK PHARM. CO., LTD.

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 Ingredients Purpose

Diphenhydramine Hydrochloride USP, 2% .....Topical analgesic

Zinc acetate, 0.1% .....Skin Protectant

Uses

Temporarily relieves pain and itching associated with: insect bites, minor burns, sunburn, minor skin irritations, minor cuts, scrapes, rashes due to poison ivy, poison oak, and poison sumac. Dries the oozing and weeping of poison ivy, poison oak, and poison sumac.

Warnings

For external use only

Do not use on large area of the body or with any other product containing diphenhydramine, even one taken by mouth.

Ask a doctor before use

on chicken pox or on measles.

When using this product

avoid contact with the eyes.

Stop use and ask a doctor if condition worsens or does not improve within 7 days, or symptoms persist for more than 7 days, or clear up and occur again within a few days.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- do not use more than directed
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily, or as directed by a doctor
- children under 2 years of age: consult a doctor
- discontinue use and consult a physician if rash or irritation develops

Other information

- store at 20º to 25ºC (68º to 77ºF)
- Lot No. and Exp. Date: see box or see crimp of tube

Distributed By:

Chain Drug Consortium, LLC.

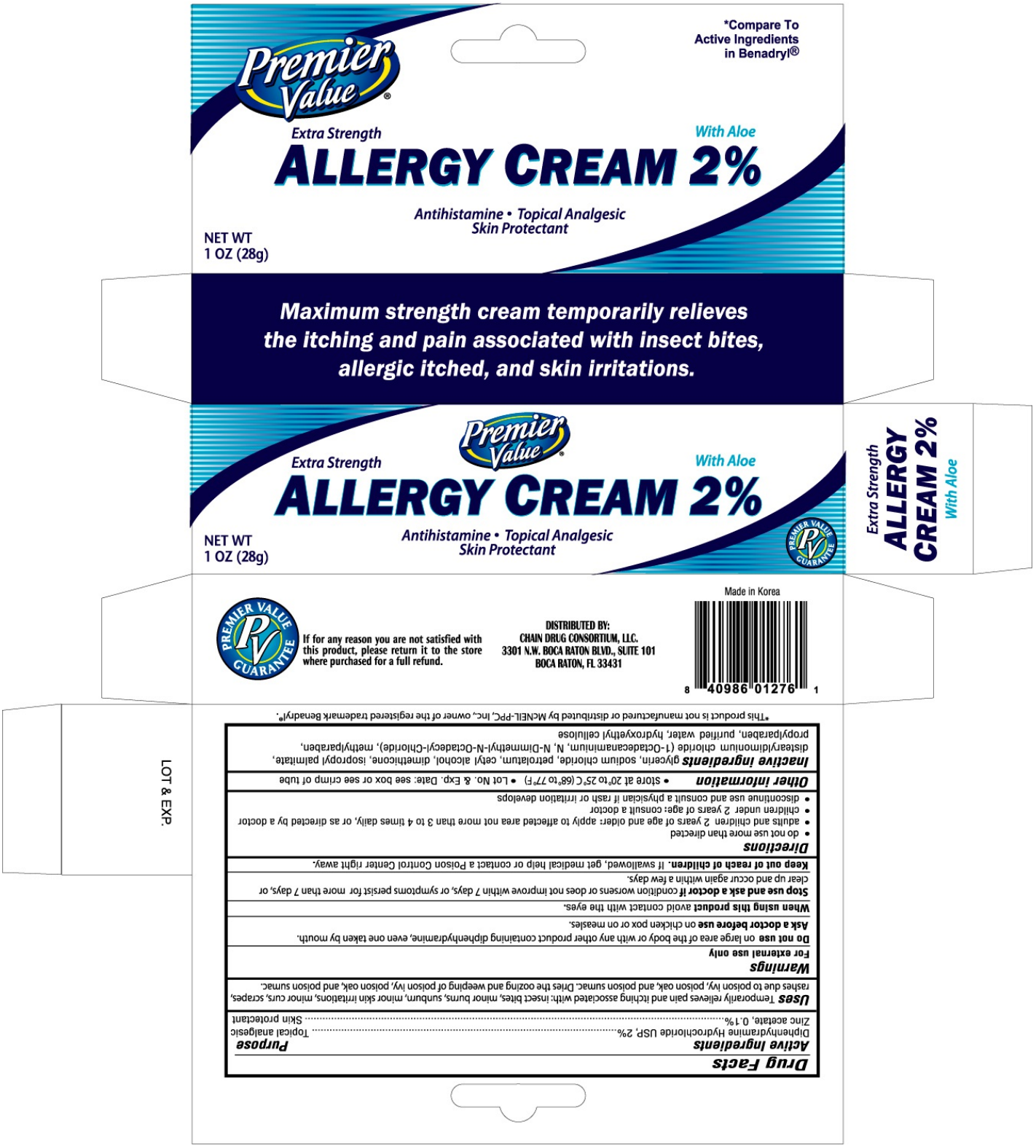
3301 N.W. Boca Raton Blvd., Suite 101

Boca Raton, FL 33431

Inactive ingredients

glycerin, sodium chloride, petrolatum, cetyl alcoho, dimethicone, isopropyl palmitate,

distearyldimonium chloride, methylparaben, propylparaben, purified water, hydroxyethyl cellulose



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PREMIER VALUE ALLERGY

diphenhydramine hydrochloride cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68169-0127

Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	2 g in 100 g
ZINC ACETATE (UNII: FM5526K07A) (ZINC - UNII:J41CSQ7QDS)	ZINC ACETATE	0.1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
PETROLATUM (UNII: 4T6H12BN9U)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68169-0127-6	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/17/2010	

Labeler - TAI GUK PHARM. CO., LTD. (631101656)

Registrant - UNITED EXCHANGE CORP. (840130579)

Establishment

Name	Address	ID/FEI	Business Operations
TAI GUK PHARM. CO., LTD.		631101656	manufacture

Revised: 9/2010 TAI GUK PHARM. CO., LTD.