PUBLIX ALLERGY- diphenhydramine hydrochloride and zinc acetate cream
Publix Super Markets 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.

Publix
allergy cream

Drug Facts

Active ingredients	***Purpose***
Diphenhydramine hydrochloride 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 areas of the body
- with any other product containing diphenhydramine, even one taken by mouth

Ask a doctor before use

- on chicken pox
- on measles

When using this product

- avoid contact with eyes

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- 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 often than directed

- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: ask a doctor

Other information

- To open: unscrew cap, use pointed end of cap to puncture seal.
- store at room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

cetyl alcohol, glyceryl stearate, glyceryl stearate/PEG-100 stearate, methylparaben, propylene glycol, propylparaben and purified water

DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.
3300 PUBLIX CORPORATE PARKWAY
LAKELAND, FL 33811

PRINCIPAL DISPLAY PANEL - 28.4g Tube Carton

EXTRA STRENGTH

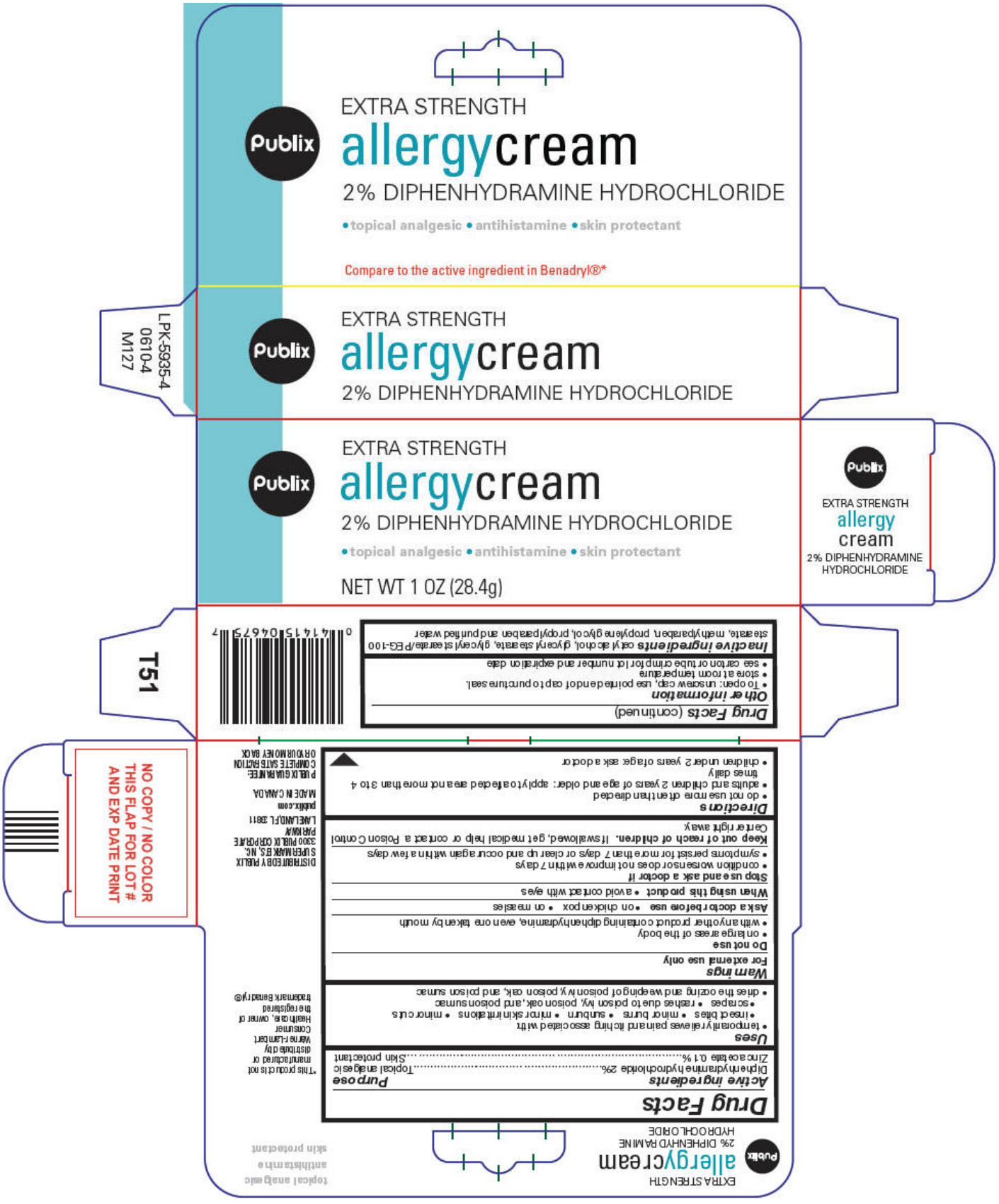
Publix

allergycream

2% DIPHENHYDRAMINE HYDROCHLORIDE

• topical analgesic • antihistamine • skin protectant

NET WT 1 OZ (28.4g)



PUBLIX ALLERGY

diphenhydramine hydrochloride and zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:41415-046
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
diphenhydramine hydrochloride (UNII: TC2D6JAD40) (diphenhydramine - UNII:8GTS82S83M)	diphenhydramine hydrochloride	20 mg in 1 g
zinc acetate (UNII: FM5526K07A) (zinc cation - UNII:13S1S8SF37)	zinc acetate	1 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
cetyl alcohol (UNII: 936JST6JCN)	
glyceryl monostearate (UNII: 230OU9XXE4)	
PEG-100 stearate (UNII: YD01N1999R)	
methylparaben (UNII: A2I8C7HI9T)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41415-046-75	1 in 1 CARTON	09/20/2005	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	09/20/2005	

Labeler - Publix Super Markets Inc (006922009)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41415-046)

Revised: 2/2019 Publix Super Markets Inc