SHOPKO ANTI-ITCH- diphenhydramine hydrochloride and zinc acetate cream Shopko Stores Operating Co., LLC

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.

Shopko® Anti-Itch 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 20° to 25°C (68° to 77°F)
- 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

Questions?

Call 1-866-923-4914

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton SHOPKO®

NDC 37012-089-02

Extra Strength

Anti-Itch Cream

Diphenhydramine hydrochloride 2% and Zinc acetate 0.1%

Antihistamine • Topical Analgesic • Skin Protectant

NET WT 1 OZ (28.4 g)



SHOPKO ANTI-ITCH

diphenhydramine hydrochloride and zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:37012-089
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
diphenhydramine hydrochloride (UNII: TC2D6JAD40) (diphenhydramine - UNII:8GTS82S83M)	diphenhydramine hydro chlo ride	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: 230 OU9 XXE4)		
PEG-100 stearate (UNII: YD01N1999R)		
methylparaben (UNII: A218 C7HI9 T)		
propylene glycol (UNII: 6DC9Q167V3)		
propylparaben (UNII: Z8IX2SC1OH)		
water (UNII: 059QF0KO0R)		

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-089-02	1 in 1 CARTON		
1		28.4 g in 1 TUBE		

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

Labeler - Shopko Stores Operating Co., LLC (023252638)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(37012-089)	