DIPHENHYDRAMINE HYDROCHLORIDE AND ZINC ACETATE- diphenhydramine hydrochloride and zinc acetate cream
Taro Pharmaceuticals U.S.A., 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.

Anti-Itch Cream 2% Diphenhydramine Hydrochloride

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**

Distributed by:
Taro Pharmaceuticals
U.S.A., Inc.
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Extra Strength

Anti-Itch Cream
Diphenhydramine Hydrochloride 2%
and Zinc Acetate 0.1%

Topical Analgesic • Skin Protectant

NET WT 1 oz (28.4 g)

NDC 51672-2089-2

Compare to the active ingredients in Extra Strength Benadryl® Itch Stopping Cream*

Anti-Itch Cream

Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%

Topical Analgesic • Skin Protectant

Relieves pain and itch from insect bites, minor skin irritations and rashes due to poison ivy, poison oak and poison sumac

LPK-5891-2
0514-2
M288

Extra Strength

Anti-Itch Cream

Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%

Topical Analgesic • Skin Protectant

NET WT 1 oz (28.4 g)

Anti-Itch Cream
Diphenhydramine Hydrochloride 2% and Zinc Acetate 0.1%
Topical Analgesic • Skin Protectant

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Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532

TARO is a registered trademark of Taro Pharmaceuticals U.S.A., Inc.
Made in Canada

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THIS FLAP FOR LOT #
AND EXP DATE PRINT

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Drug Facts (continued)

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*This product is not manufactured or distributed by Johnson & Johnson, owner of the registered trademark Benadryl®

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Extra Strength
Topical Analgesic • Skin Protectant

DIPHENHYDRAMINE HYDROCHLORIDE AND ZINC ACETATE

diphenhydramine hydrochloride and zinc acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2089
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:51672-2089-2	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 - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceutical Inc.		206263295	MANUFACTURE(51672-2089)

Revised: 1/2020 Taro Pharmaceuticals U.S.A., Inc.