

TOPCARE ANTI-ITCH- diphenhydramine hydrochloride and zinc acetate cream
Topco Associates 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.

TopCare®
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 **1-888-423-0139**

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

NDC 36800-506-02

TopCare®
health™

EXTRA STRENGTH

Anti-Itch Cream 2%

DIPHENHYDRAMINE HYDROCHLORIDE 2% & ZINC ACETATE 0.1%

Topical Analgesic & Skin Protectant

• OUR PHARMACISTS
RECOMMEND •

NET WT 1 OZ (28.4 g)

COMPARE TO EXTRA STRENGTH
BENADRYL® ITCH STOPPING
CREAM ACTIVE INGREDIENTS*

Itch Relief Cream

RELIEVES:

- Insect Bites, Minor Skin Irritations & Rashes Due to Poison Ivy, Poison Oak & Poison Sumac

Insect Bites



Poison Ivy, Oak & Sumac



Sunburn



Skin Irritations



LPK-8947-3
1118-3
18



EXTRA STRENGTH

Anti-Itch Cream 2%

DIPHENHYDRAMINE HYDROCHLORIDE 2% & ZINC ACETATE 0.1%

Topical Analgesic & Skin Protectant



Anti-Itch Cream 2%
DIPHENHYDRAMINE
HYDROCHLORIDE 2%
& ZINC ACETATE 0.1%

NDC 36800-05119-02

NET WT 1 OZ (28.4 g)

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MADE IN CANADA



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more information



This TopCare® product is laboratory tested to guarantee its highest quality. Your total satisfaction is guaranteed.

NO COPY / NO COLOR
THIS FLAP FOR LOT #
AND EXP DATE PRINT

<p>Drug Facts</p> <p>Active ingredients Diphenhydramine hydrochloride 2%, Topical analgesic Zinc acetate 0.1%, Skin protectant</p> <p>Purpose Topical analgesic & Skin Protectant</p>		<p>Uses • temporarily relieve 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</p> <p>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 or nurse • on children's face • on measles • on children's eyes When using this product avoid contact with eyes</p> <p>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</p>
<p>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</p> <p>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</p> <p>Inactive ingredients cetyl alcohol, glyceryl stearate, glyceryl stearate, PEG-100 stearate, methylparaben, propylene glycol, propylparaben and purified water</p> <p>Questions? Call 1-888-423-0139</p>		<p>Drug Facts (continued) Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p>

Anti-Itch Cream 2%
Topical Analgesic & Skin Protectant



TOPCARE ANTI-ITCH

diphenhydramine hydrochloride and zinc acetate cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-506	
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)				
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:36800-506-02	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 - Topco Associates LLC (006935977)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(36800-506)