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	Topical
2%	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?

1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC 7711 GROSS POINT ROAD SKOKIE, IL 60077

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

TopCare®

EXTRA STRENGTH

Anti-Itch Cream 2%

DIPHENHYDRAMINE HYDROCHLORIDE 2% AND ZINC ACETATE 0.1%

QUALITY GUARANTEED

COMPARE TO BENADRYL® active ingredient*

NET WT 1 OZ (28.4 g)

TopCare_® — **Topical Analgesic and Skin Protectant** Relief of skin irritation Relieves pain and itch from insect bites. minor skin irritations and rashes due to poison ivy, poison oak and poison sumac **EXTRA STRENGTH** TopCare. Anti-Itch Cream 2% Anti-Itch Cream 2% DIPHENHYDRAMINE DIPHENHYDRAMINE HYDROCHLORIDE 2% HYDROCHLORIDE 2% AND ZINC ACETATE 0.1 1/4 AND ZINC ACETATE 0.1% COMPARE TO BENADRYL® NETWT1 OZ (28.4 g) Inactive ingredients cetyl alcohol, glyceryl stearate, glyceryl stearate/PEG-100 stearate/PEG-100 To open: unscrew cap, use pointed end of cap to puncture seal. store at 20° to 26°C (68° to 77°F) see carton or tube crimp for lot number and expiration date Other information Drug Facts (continued) guaranteed. children under 2 years of age: ask a doctor guarantee its highest quality Your total satisfaction is Vines daily • adults and children 2 years of age and older: apply to affected area not more than 3 to 4 This Top Care® product is laboratory tested to Made in Canada. Center right away. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control тоо.coqataseльоqat symptoms persist for more than 7 days or clear up and occur again within a few days 1-888-423-0139 condition worsens or does not improve within 7 days COESTIONS? CTOPCO TARITITI Stop use and ask a doctor if SKOKIE' IT 60077 When using this product avoid contact with eyes TATA GROSS POINT ROAD TOPCO A SSOCIATES LLC Ask a doctor before use • on chicken pox • on measles DISTRIBUTED BY with any other product containing diphenhydramine, even one taken by mouth · ou large areas of the body Do not use distributed by Johnson, where registered owner of the registered banadryl® For external use only Marnings *This product is not manufactured or dries the oozing and weeping of poison ivy, poison oak, and poison sumac scrapes rashes due to poison ivy, poison oak, and poison sumac usect pites • minor prime • surprim • minor skin intrations • minor cuts ...Skin protectant .%2 sbiroldcorbydramine hydrochloride 2%. Zinc acetate 0.1%...... . Topical analgesic Purpose

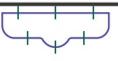
ехтвь ятлематн **Cream Pnti-Itch Cream**вригинграмиие нүрөнсүнгөйре 2%

вир zing acetate 0.1%

PK-5947-

<u> 151</u>

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



TopCare.

Urug Facts

TOPCARE ANTI-ITCH

diphenhydramine hydrochloride and zinc acetate cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:36800-506
Route of Administration	TOPICAL	DEA Schedule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Diphenhydramine Hydrochloride (Diphenhydramine)	Diphenhydramine Hydrochloride	20 mg in 1 g	
Zinc Acetate (Zinc Cation)	Zinc Cation	1 mg in 1 g	

Inactive Ingredients		
Ingredient Name	Strength	
cetyl alcohol		
glyceryl monostearate		
methylparaben		
propylene glycol		
propylparaben		
water		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:36800-506-02	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 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)

Revised: 1/2013 Topco Associates LLC