

TOPCARE HYDROCORTISONE INTENSIVE HEALING FORMULA- hydrocortisone 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®
Hydrocortisone Intensive Healing Formula

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch cream

Uses

- temporary relief of itching associated with minor skin irritations and rashes due to
 - eczema
 - insect bites
 - poison ivy, poison oak, or poison sumac
 - soaps
 - detergents
 - cosmetics
 - jewelry
 - seborrheic dermatitis
 - psoriasis
 - external genital and anal itching
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the eyes
- by putting this product into the rectum by using fingers or any mechanical device or applicator

Ask a doctor before use if you have

- a vaginal discharge
- rectal bleeding
- diaper rash

When using this product consult a doctor before exceeding recommended dosage

Stop use and ask a doctor if

- condition gets worse
- condition persists for more than 7 days

- condition clears up and occurs again within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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: do not use. Consult a doctor

For external anal itching:

- Adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product

Children under 12 years of age: consult a doctor

Other information

- To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- store at room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

aloe barbadensis, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, chamomile (anthesis nobilis) oil, citric acid, corn (zea mays) oil, glycerin, glyceryl stearate, isopropyl palmitate, maltodextrin, methylparaben, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

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®

MAXIMUM STRENGTH

Hydrocortisone Cream 1%

Intensive Healing Formula[†]

ANTIPRURITIC (ANTI-ITCH)

NET WT 1 OZ (28.4 g)

QUALITY

GUARANTEED

COMPARE TO CORTIZONE•10[®]
INTENSIVE HEALING FORMULA*
active ingredient

TopCare®

itch and rash relief

Intensive Healing Formula[†]

- †Contains healing moisturizers enriched with Vitamins A, D & E
- With antioxidants and chamomile

Maximum Strength Relief of:

- Dry, Itchy Skin • Eczema & Psoriasis • Inflammation, Irritation & Redness

TopCare®

MAXIMUM STRENGTH

Hydrocortisone Cream 1%

Intensive Healing Formula[†]

ANTIPRURITIC (ANTI-ITCH)

NET WT 1 OZ (28.4 g)



COMPARE TO CORTIZONE•10®
INTENSIVE HEALING FORMULA*
active ingredient



Drug Facts (continued)

Other information • To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube • store at room temperature • see carton or tube crimp for lot number and expiration date

Inactive ingredients aloe barbadensis, cetylalcohol/sodium lauryl sulfate/sodium cetylal sulfate, chamomile (antheris nobilis) oil, citric acid, corn (zea mays) oil, glycerin, glyceryl stearate, isopropyl palmitate, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

The product is not manufactured or distributed by Chatham, Inc. distributed by Chatham, Inc. distributor of Cortizone-10® Intensive Healing Formula.

DISTRIBUTED BY
TOPCO ASSOCIATES LLC
7711 GROSS POINT ROAD
SKOKIE, IL 60077
© TOPCO, PAR111
QUESTIONS?
1-888-423-0139
topcare@topco.com
Made in Canada.

The TopCare® product is laboratory tested to guarantee its high est quality. Your total satisfaction is guaranteed.

Warnings
For external use only
Do not use
• in the eyes
• by putting this product into the rectum by using fingers or any mechanical device or applicator

Ask a doctor before use if you have
• a vaginal discharge • rectal bleeding • diaper rash

When using this product consult a doctor before exceeding recommended dosages

Stop use and ask a doctor if
• condition gets worse • condition persists for more than 7 days
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Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

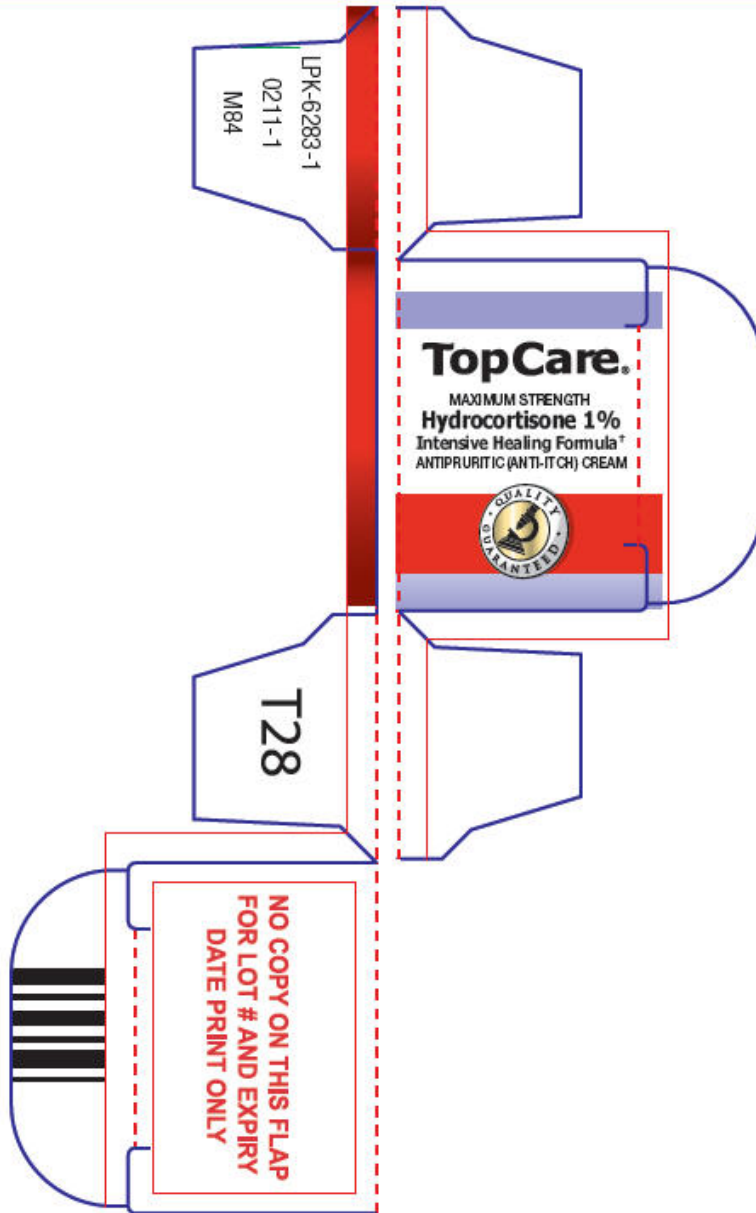
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TopCare®
MAXIMUM STRENGTH
Hydrocortisone 1%
Intensive Healing Formula†
 ANTI-ITCH CREAM

Drug Facts
Active ingredient
 Hydrocortisone 1%.....

Purpose
 Anti-itch cream

Uses
 • Temporary relief of itching associated with minor skin irritations and rashes due to
 • eczema • insect bites • poison ivy, poison oak, or poison sumac • soaps • detergents • cosmetics
 • jewelry • seborrheic dermatitis • psoriasis • external genital and anal itching
 • other uses of this product should be only under the advice and supervision of a doctor



TOPCARE HYDROCORTISONE INTENSIVE HEALING FORMULA			
hydrocortisone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
cetostearyl alcohol (UNII: 2DMT128M1S)	
sodium lauryl sulfate (UNII: 368GB5141J)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
chamomile flower oil (UNII: 60F80Z61A9)	
citric acid monohydrate (UNII: 2968PHW8QP)	
corn oil (UNII: 8470G57WFM)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
maltodextrin (UNII: 7CVR7L4A2D)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
stearyl alcohol (UNII: 2KR89I4HIY)	
vitamin A palmitate (UNII: 1D1K0N0VVC)	
cholecalciferol (UNII: 1C6V77QF41)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-099-02	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	08/23/1995	

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(36800-099)

Revised: 1/2013

Topco Associates LLC