

**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.*

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**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<sup>†</sup>**

**ANTIPRURITIC (ANTI-ITCH)**

**NET WT 1 OZ (28.4 g)**

**QUALITY**

**GUARANTEED**

**COMPARE TO CORTIZONE•10<sup>®</sup>**  
**INTENSIVE HEALING FORMULA\***  
*active ingredient*

# TopCare®

## itch and rash relief

# Intensive Healing Formula<sup>†</sup>

- †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<sup>†</sup>

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., distributor of Cortizone-10® Intensive Healing Formula.

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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 highest 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

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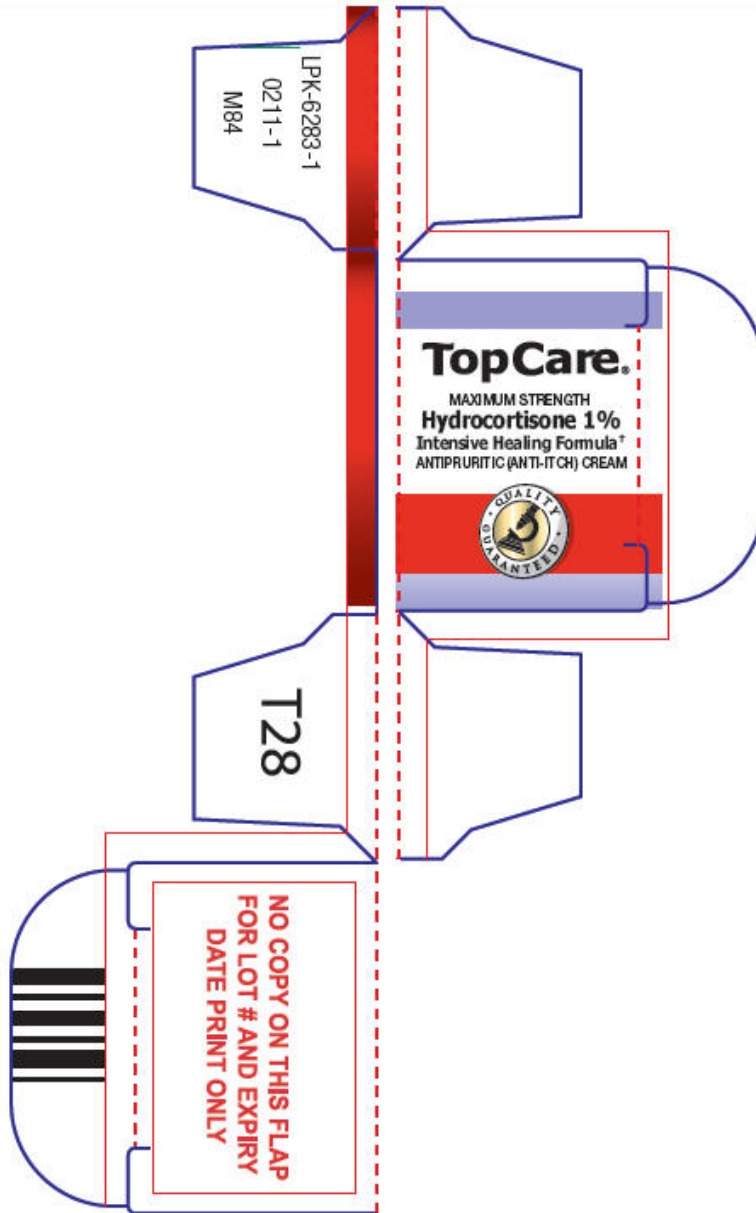
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**Drug Facts**  
**Active ingredient**  
 Hydrocortisone 1%  
**Purpose**  
 Anti-itch cream  
 (ANTI-ITCH) CREAM  
 ANTI-PRURITIC

**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

**MAXIMUM STRENGTH**  
**Hydrocortisone 1%**  
**Intensive Healing Formula†**



<b>TOPCARE HYDROCORTISONE INTENSIVE HEALING FORMULA</b>			
hydrocortisone cream			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG LABEL	<b>Item Code (Source)</b>	NDC:36800-099
<b>Route of Administration</b>	TOPICAL	<b>DEA Schedule</b>	

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (Hydrocortisone)	Hydrocortisone	1 g in 100 g

**Inactive Ingredients**

Ingredient Name	Strength
cetostearyl alcohol	
sodium lauryl sulfate	
sodium cetostearyl sulfate	
chamomile flower oil	
citric acid monohydrate	
corn oil	
glycerin	
glyceryl monostearate	
isopropyl palmitate	
maltodextrin	
methylparaben	
mineral oil	
paraffin	
petrolatum	
propylene glycol	
propylparaben	
water	
stearyl alcohol	
vitamin A palmitate	
cholecalciferol	
.alpha.-tocopherol acetate	

**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