TOPCARE HYDROCORTISONE PLUS 12 MOISTURIZERS- 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 Plus 12 Moisturizers

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 (anthemis 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
topcare@topco.com

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

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

TopCare®

MAXIMUM STRENGTH

Hydrocortisone 1%
Plus 12 Moisturizers
ANTIPRURITIC (ANTI-ITCH) CREAM

NET WT 1 OZ (28.4 g)

QUALITY
GUARANTEED

COMPARE TO
CORTIZONE•10® PLUS
active ingredient*

TopCare®

itch and rash relief

With 12 Moisturizers

- Contains healing moisturizers enriched with Vitamins A, D & E
- Fast relief of skin irritation, inflammation, and redness

Maximum Strength Relief of Itches and Rashes Due To:

- Eczema • Psoriasis • Seborrheic Dermatitis • Poison Ivy, Oak, and Sumac • Insect Bites
- External Genital and Anal Itching • Soaps • Detergents • Cosmetics • Jewelry

TopCare®

MAXIMUM STRENGTH

Hydrocortisone 1%

Plus 12 Moisturizers

ANTIPRURITIC (ANTI-ITCH) CREAM

NET WT 1 OZ (28.4 g)

QUALITY GUARANTEED

COMPARE TO CORTIZONE•10® PLUS active ingredient*

Drug Facts (continued)

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*This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Cortizone-10® PLUS

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TOP COAST SOLUTIONS LLC
2711 GROSS POINT ROAD
SKOKIE, IL 60077
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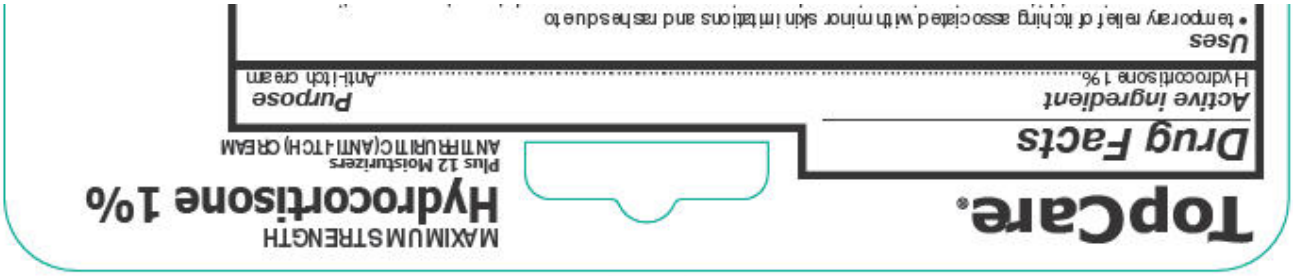
QUESTIONS?
1-888-423-0139
topcaresupport.com

Made in Canada.

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



TOPCARE HYDROCORTISONE PLUS 12 MOISTURIZERS

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG LABEL	**Item Code (Source)**	NDC:36800-051
Route of Administration	TOPICAL	**DEA Schedule**	

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:36800-051-18	1 in 1 CARTON		
1		28.4 g in 1 TUBE		
2	NDC:36800-051-06	1 in 1 CARTON		
2		42.6 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/03/1989	

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(36800-051)