

TOPCARE HYDROCORTISONE 1% WITH ALOE- 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 1% with Aloe

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, citric acid, glycerin, glyceryl stearate, methylparaben, mineral oil, paraffin, propylparaben, purified water, stearyl alcohol

Questions?

Call **1-866-923-4914**

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

NDC 36800-059-02

TopCare®
health™

MAXIMUM STRENGTH

Hydrocortisone Cream 1%
ANTIPRURITIC (ANTI-ITCH)

with Aloe

NET WT 1 OZ (28.4 g)

•OUR PHARMACISTS•
RECOMMEND

COMPARE TO CORTIZONE-10®
ACTIVE INGREDIENT*

Itch & Rash Relief Cream with Aloe

Effective Relief of Skin Irritation, Rashes, Inflammation, Itching & Redness

RELIEVES:

- Rashes & Redness • Eczema & Psoriasis
- Inflammation & Irritation • Dry, Itchy Skin
- Poison Ivy & Insect Bites



MAXIMUM STRENGTH

Hydrocortisone Cream 1% ANTIPRURITIC (ANTI-ITCH)

with Aloe



Hydrocortisone Cream 1%
with Aloe
ANTIPRURITIC (ANTI-ITCH)

NET WT 1 OZ (28.4 g)

LPK-3721-5
12/18/5
15

NDC:36800-059-02

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

NO COPY ON THIS FLAP
FOR LOT # AND EXPIRY
DATE PRINT ONLY

<p>Drug Facts</p> <p>Active ingredient Hydrocortisone 1% (Anti-Itch)</p> <p>Purpose Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p>Directions For itching of skin irritation, inflammation, and rashes: • 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 • TopCare uses screw caps, pull tabs to remove lid seal, and screw cap back onto tube • store at room temperature • see carton or tube crimp for lot number and expiration date</p> <p>Inactive ingredients sulfacetamide sodium, salicylic acid, sodium lauryl sulfate, sodium hydroxide, methylparaben, mineral oil, paraffin wax, propylparaben, purified water, sodium butyrate, stearyl alcohol</p> <p>Questions? Call 1-888-423-0139 *This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark Cortizone-10®.</p>	<p>Warnings For external use only</p> <p>Do not use • in the genital area if you have a vaginal discharge. Consult a doctor. • for the treatment of diaper rash. Consult a doctor.</p> <p>When using this product • avoid contact with eyes • do not use more than directed unless told to do so by a doctor • do not put directly into the rectum by using fingers or any mechanical device or applicator</p> <p>Stop use and ask a doctor if • condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor • rectal bleeding occurs</p>
<p>Uses temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: • poison ivy, oak, sumac • insect bites • contact dermatitis • eczema • psoriasis • sunburn • temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to: • eczema • psoriasis • sunburn • temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to: • eczema • psoriasis • sunburn</p>	<p>other uses of the product: consult your doctor for the advice and supervision of a doctor</p> <p>temporarily relieves external and genital itching • eczema • contact dermatitis • insect bites • psoriasis • sunburn</p>

Hydrocortisone Cream 1%



TOPCARE HYDROCORTISONE 1% WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-059
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	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)	
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A218C7H9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-059-03	1 in 1 CARTON	08/23/1995	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:36800-059-02	1 in 1 CARTON	08/23/1995	
2		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	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(36800-059)