

TOPCARE HYDROCORTISONE- hydrocortisone ointment

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

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch ointment

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

Fractionated Coconut Oil, Methylparaben, Propylparaben, White Petrolatum

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%

ANTIPRURITIC (ANTI-ITCH) OINTMENT

NET WT 1 OZ (28.4 g)

QUALITY GUARANTEED

**COMPARE TO
CORTIZONE•10®
active ingredient***

TopCare®

maximum strength Itch & Rash Relief

Fast relief of skin irritation, rashes, inflammation, itching and redness

Effective relief of itches and rashes due to:

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

TopCare®

MAXIMUM STRENGTH

Hydrocortisone 1%

ANTIPRURITIC (ANTI-ITCH) OINTMENT

NET WT 1 OZ (28.4 g)



COMPARE TO
CORTIZONE-10®
active ingredient*



Drug Facts (continued)

Other information

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Inactive ingredients Fractionated Coconut Oil, Methylparaben, Propylparaben, White Petrolatum

This product is not manufactured or distributed by Pfizer Consumer Health Care, Cortez, IL 60077. © TOPCO TARI 11. 1-888-423-0139. topcare@pe.com. Made in Canada. This TopCare® product is laboratory tested to guarantee the highest quality. Your retail 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 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
Keep out of reach of children. If swallowed, get medical help or contact 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

TopCare.
 MAXIMUM STRENGTH
Hydrocortisone 1%
 ANTIPRURITIC (ANTI-ITCH) OINTMENT

Drug Facts

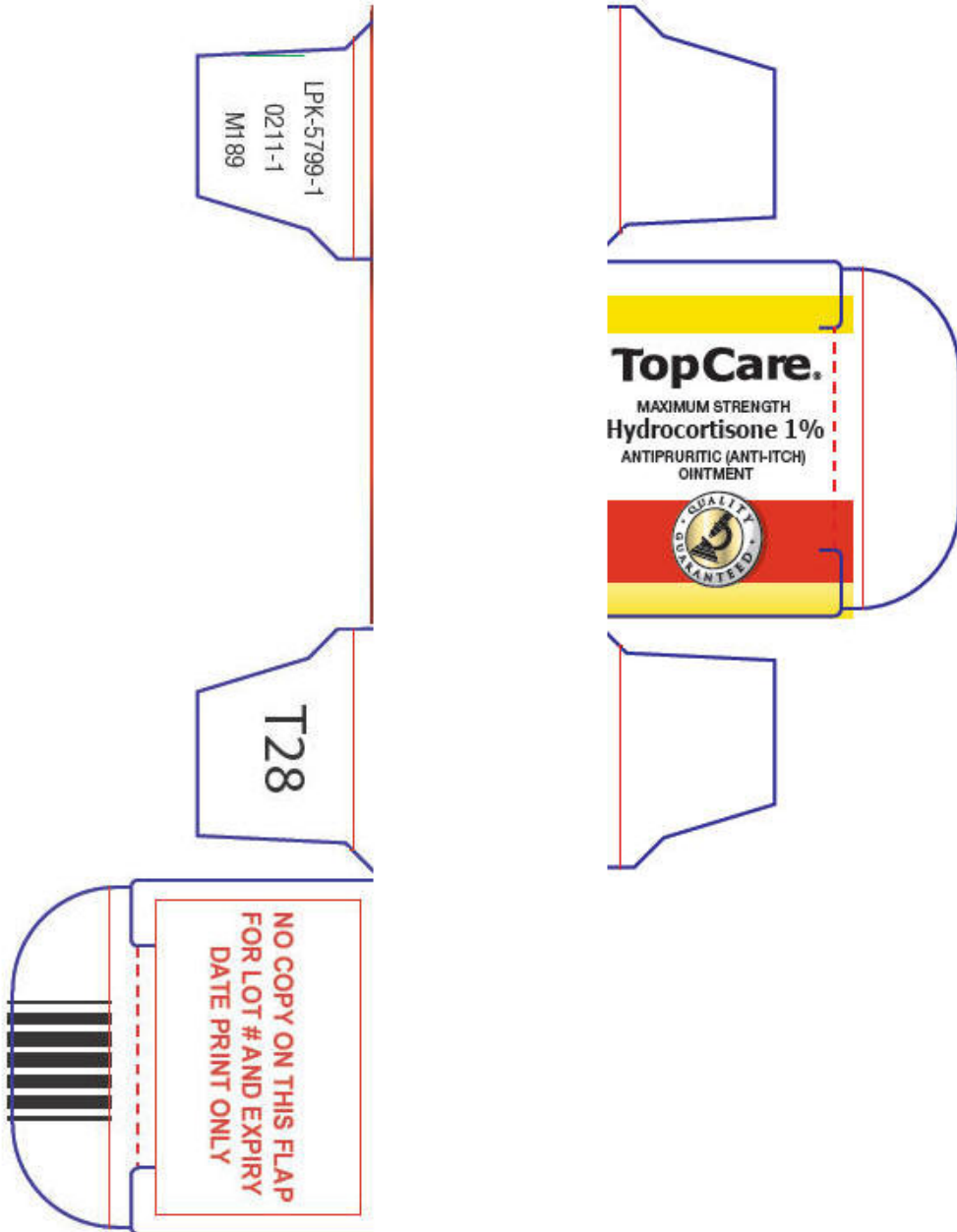
Active ingredient
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Warnings



TOPCARE HYDROCORTISONE

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-018
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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
Medium-chain triglycerides (UNII: C9H2L21V7U)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-018-02	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	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(36800-018)

Revised: 1/2013

Topco Associates LLC