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

Uses

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

Warnings

For external use only

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.

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

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

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

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
- **for external anal and genital itching, adults:**
  - when practical, clean 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 applying
  - apply to affected area not more than 3 to 4 times daily
  - children under 12 years of age: ask a doctor

Other information

- To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- store between 20° to 25°C (68° to 77°F)
- 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?

Call **1-888-423-0139**

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

TopCare
health™

MAXIMUM STRENGTH

• OUR PHARMACISTS
RECOMMEND •

NDC 36800-099-02

Hydrocortisone 1% Cream

ANTIPRURITIC (ANTI-ITCH)

Intensive Healing Formula†

NET WT 1 OZ (28.4 g)

COMPARE TO CORTIZONE•10®
INTENSIVE HEALING FORMULA
ACTIVE INGREDIENT*

Itch & Rash Relief Cream
Intensive Healing Formula†

Relieves Itch
†Contains Healing Moisturizers Enriched with Vitamins A, D & E With Antioxidants & Chamomile

RELIEVES:
- Rashes & Redness • Eczema & Psoriais
- Inflammation & Irritation • Dry, Itchy Skin

NDC 36800-099-02

TopCare health™

MAXIMUM STRENGTH

Hydrocortisone 1% Cream

ANTIPRURITIC (ANTI-ITCH)

Intensive Healing Formula†

NET WT 1 OZ (28.4 g)

0 36800 33089 4

* This product is not manufactured or distributed by Chattem, Inc., owner of the registered trademark Cortizone•10® Intensive Healing Formula.

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ELK GROVE VILLAGE, IL 60007
©TOPCO TARA0718 QUESTIONS? 1-888-423-0139
topcare@topco.com www.topcarebrand.com
MADE IN CANADA

Scan here for more information

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

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- detergents
- jewelry
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- soaps
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- children under 2 years of age: ask 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: 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)	
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: 2KR89I4H1Y)	
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	08/23/1995	
1		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(36800-099)

Revised: 4/2019

Topco Associates LLC