

TOPCARE HYDROCORTISONE- 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.

Topco Associates LLC. Hydrocortisone 1% Cream 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 be only 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. Ask a doctor.
- for the treatment of diaper rash. Ask a doctor.

When using this product

- avoid contact with the 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: do not use, 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

- store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe barbadensis leaf juice, aluminum sulfate, calcium acetate, cetearyl alcohol, cetyl alcohol, cholecalciferol, dextrin, glycerin, isopropyl palmitate, light mineral oil, maltodextrin, methylparaben, propylene glycol, propylparaben, purified water, retinyl palmitate, sodium cetearyl sulfate, sodium lauryl sulfate, tocopherol, white petrolatum, white wax, zea mays (corn) oil

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO CORTIZONE • 10[®] PLUS ACTIVE INGREDIENT

Itch & Rash Relief Cream

Plus 10 Moisturizers

Contains Healing Moisturizers

Enriched with Vitamins A, D & E

Fast Relief of Skin Irritation, Inflammation, & Redness

TopCare® health

MAXIMUM STRENGTH

Hydrocortisone 1% Cream

ANTI-ITCH CREAM

Plus 10 Moisturizers

NET WT 1 OZ (28 g)

COMPARE TO CORTIZONE*10® PLUS
ACTIVE INGREDIENT*

Itch & Rash Relief Cream

Plus 10 Moisturizers

Contains Healing Moisturizers
Enriched with Vitamins A, D & E
Fast Relief of Skin Irritation,
Inflammation, & Redness

RELIEVES:

- Dry, Itchy Skin • Skin Irritation & Rashes
- Eczema & Psoriasis • Moisturizes While It Relieves
- Enriched with Aloe



MAXIMUM STRENGTH

Hydrocortisone 1% Cream

ANTI-ITCH CREAM

Plus 10 Moisturizers

NET WT 1 OZ (28 g)

NDC 36800-981-64

CODE AREA



Scan here for more information or call 1-888-423-0139

DISTRIBUTED BY TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL 60007
©TOPCO PERA0521
QUESTIONS? 1-888-423-0139
topcare@topco.com



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

*This product is not manufactured or distributed by Chatterm, Inc., distributor of Cortizone*10® Plus.

CODE AREA

Drug Facts (continued)

Keep out of reach of children. If swallowed, get medical help or contact 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: do not use, ask a doctor
- for external use on an adult and child:
 - when practical, clean the affected area with mild soap and warm water and rinse thoroughly
 - gently dry by patting or blotting with blot tissue or a soft cloth before applying
 - apply to affected areas not more than 3 to 4 times daily
 - children under 12 years of age: ask a doctor

Other information ■ Store at 20°-25°C (68°-77°F)

Inactive ingredients ■ Hydrocortisone base, aluminum sulfate, calcium acetate, cetyl alcohol, cholesterol, dectin, glycerin, isopropyl palmitate, light mineral oil, methylparaben, propylene glycol, polyphosphoric acid, purified water, red 40, sorbitol, stearyl alcohol, stearic acid, titanium dioxide, white petrolatum, white wax, zea mays (corn) oil

Questions or comments? 1-888-423-0139

Drug Facts

Active ingredient Hydrocortisone 1% (Anti-Itch)

Uses

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

Warnings

- Do not use in the genital area if you have a vaginal discharge. Ask a doctor.
- For the treatment of diaper rash, ask a doctor.
- When using this product, avoid contact with the 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:
 - rectal bleeding occurs
 - 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.

Purpose Anti-Itch

Hydrocortisone 1% Cream



TOPCARE HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-981
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM SULFATE (UNII: 34S289N54E)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	
CORN OIL (UNII: 8470G57WFM)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-981-64	1 in 1 CARTON	03/20/2020	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
-----------	---------------------------------	-----------------	---------------

Category	Citation	Date	Date
OTC monograph not final	part348	03/20/2020	

Labeler - Topco Associates LLC (006935977)

Revised: 3/2022

Topco Associates LLC