

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 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 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 (1-800-222-1222).

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, consult 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: consult a doctor

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

water, cetearyl alcohol, cetareth-20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, aloe barbadensis leaf juice

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

COMPARE TO MAXIMUM STRENGTH CORTIZONE•10[®] ACTIVE INGREDIENT

Relieves Itch Fast

with Aloe

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

TopCare® health

MAXIMUM STRENGTH

Hydrocortisone 1% Cream

ANTI-ITCH CREAM

with Aloe

NET WT 1 OZ (28 g)

COMPARE TO MAXIMUM STRENGTH
CORTIZONE•10® ACTIVE INGREDIENT*

Relieves Itch Fast

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 1% Cream

ANTI-ITCH CREAM

with Aloe

NET WT 1 OZ (28 g)

NDC 36800-18240-64

CODE AREA

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



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



0 36800 18240 0
31964 88 C2



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



Hydrocortisone 1% Cream

Drug Facts

Active ingredient

Hydrocortisone 1%.....Anti-itch

Purpose

Anti-itch

Uses ■ temporarily relieve 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 relieve 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
- red, itchy, bleeding occurs

Drug Facts (continued)

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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, consult 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: consult a doctor

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

Inactive ingredients water, cetylalcohol, cetylareth-20, cetylalmitate, glycerin, isopropylmyristate, isostearyl sebacate, methylparaben, aloe barbadensis leaf juice

Questions or comments? 1-888-423-0139

*This product is not manufactured or distributed by Chateau, Inc., distributor of Maximum Strength Cortizone•10®.

CODE AREA

TOPCARE HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-524
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
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-524-64	1 in 1 CARTON	02/14/2020	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:36800-524-26	2 in 1 CARTON	02/14/2020	
2		56 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	02/14/2020	

Labeler - Topco Associates LLC (006935977)