

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

Directions

Click here to enter Directions

Warnings

For external use only

Do not use

- for the treatment of diaper rash. Ask a doctor.
- in the genital area if you have a vaginal discharge. 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, avena sativa (oat) kernel extract, benzyl alcohol, butylated hydroxytoluene, cetostearyl alcohol, cetyl alcohol, chamomilla recutita (matricaria) flower extract, diazolidinyl urea, dimethicone, distearyldimonium chloride, edetate disodium, glycerin, glyceryl monostearate, hydrolyzed collagen, hydrolyzed elastin, hydrolyzed jojoba esters, jojoba esters, magnesium ascorbyl phosphate, menthyl lactate, methyl gluceth-20, methylparaben, petrolatum, polysorbate 60, potassium hydroxide, PPG-12/SMDI copolymer, propylparaben, purified water, retinyl palmitate, stearamidopropyl PG-dimonium chloride phosphate, steareth-2, steareth-21, stearyl alcohol, tocopheryl acetate

Questions or comments?

1-888-423-0139

Package/Label Principal Display Panel

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, C & E

With Antioxidants & Chamomile

MAXIMUM STRENGTH

OUR PHARMACISTS RECOMMEND

Hydrocortisone 1% Cream

ANTI-ITCH CREAM

Intensive Healing Formula[†]

NET WT 1 OZ (28 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, C & E
With Antioxidants & Chamomile

RELIEVES:

- Rashes & Redness • Eczema & Psoriasis
- Inflammation & Irritation • Dry, Itchy Skin



MAXIMUM STRENGTH



Hydrocortisone 1% Cream

ANTI-ITCH CREAM

Intensive Healing Formula†

NET WT 1 OZ (28 g)

NDC 36800-3308-64



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36964 88 C1



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® Intensive Healing Formula.



Scan here for more information



Drug Facts

Active Ingredient
Hydrocortisone 1%
Purpose
Anti-Itch

Uses

- to 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
 - subacute dermatitis
- to 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
 - for the treatment of diaper rash. Ask a doctor.
 - in the genital area if you have a vaginal discharge. Ask a doctor.
- When using this product**
- avoid contact with the eyes
 - do not use more than directed unless told to do so by doctor
 - do not put directly in 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.**

Drug Facts (continued)

- Directions**
- for itching of skin irritation, inflammation, and rashes:
 - adults and children 2 years of age and older: apply to affected area of more than 3 to 4 times daily
 - children under 2 years of age: do not use, ask 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 doctor

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

Inactive Ingredients: aloe barbadensis leaf juice, a vanassa (vanilla) leaf extract, benzyl alcohol, butylated hydroxytoluene, cetearyl alcohol, cetyl alcohol, chamomile (chamaemelum) flower extract, diazolidinyl urea, dimethicone, distearyldimonium chloride, edetate disodium, glycerin, glyceryl monostearate, hydrolyzed collagen, hydrolyzed elastin, hydrolyzed lecithin esters, jojoba esters, magnesium ascorbyl phosphate, menthyl lactate, methylgluceth-20, methylparaben, polybutene-2, polybutene-3, potassium hydroxide, PEG-12 SMDI copolymer, propylparaben, purified water, retinyl palmitate, stearamidopropyl dimethylamine chloride phosphate, stearic acid, stearyl-2, stearyl-21, stearyl alcohol, tosylalanyl acetate

Questions or comments? 1-888-423-0139

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hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-939
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OAT (UNII: Z6J799EAJK)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHAMOMILE (UNII: FGL3685T2X)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)	
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
STEARAMIDOPROPYL PROPYLENE GLYCOL-DIMONIUM CHLORIDE PHOSPHATE (UNII: W6000VEI5Y)	
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
HYDROLYZED BOVINE ELASTIN (BASE; 1000 MW) (UNII: ZR28QKN0WT)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-939-64	1 in 1 CARTON	03/15/2020	
1		28 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	03/15/2020	

Labeler - Topco Associates LLC (006935977)

Revised: 3/2020

Topco Associates LLC