

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

OUR PHARMACISTS RECOMMEND

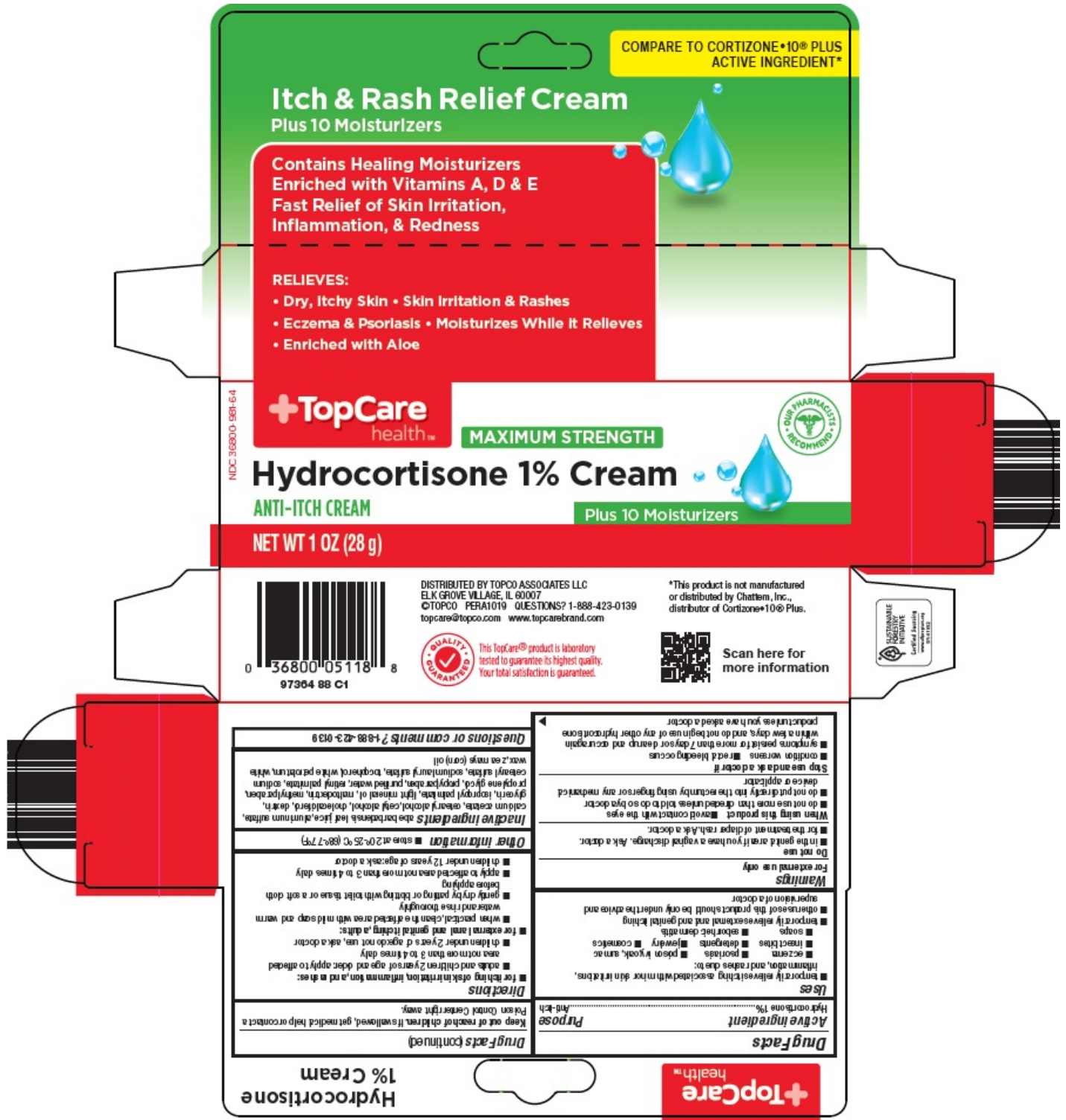
MAXIMUM STRENGTH

Hydrocortisone 1% Cream

ANTI-ITCH CREAM

Plus 10 Moisturizers

NET WT 1 OZ (28 g)



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: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	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)	
METHYL PARABEN (UNII: A218C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (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 Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/20/2020	

Labeler - Topco Associates LLC (006935977)

Revised: 3/2020

Topco Associates LLC