

CORTIZONE 10 COOLING- hydrocortisone gel
Chattem, Inc.

Cortizone 10 Cooling Gel

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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

Inactive ingredients

alcohol denat. (15%), aloe barbadensis leaf juice, avena sativa (oat) kernel extract, dextrin, dimethicone, disodium EDTA, glycerin, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, isohexadecane, maltodextrin, menthyl lactate, methyl gluceth-20, methylparaben, polysorbate 60, PPG-3 benzyl ether myristate, propylparaben, sodium citrate, water

PRINCIPAL DISPLAY PANEL

MAXIMUM STRENGTH

Cortizone 10

COOLING

ITCH RELIEF GEL

1% Hydrocortisone

Anti-Itch Gel

Net wt 1 oz (28 g)



CORTIZONE 10 COOLING

hydrocortisone gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0033
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BP) (HYDROCORTISONE - UNII:W4X0X7BP)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
OAT (UNII: Z6J799EAJK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	

GLYCERIN (UNII: PDC6A3C00X)
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)
ISOHEXADECANE (UNII: 918X1OUF1E)
MALTODEXTRIN (UNII: 7CVR7L4A2D)
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
METHYL PARABEN (UNII: A2I8C7HI9T)
POLYSORBATE 60 (UNII: CAL22UVI4M)
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)
WATER (UNII: 059QF0KO0R)

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0033-2	1 in 1 CARTON	01/01/2023	
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 Drug	M017	01/01/2023		

Labeler - Chattem, Inc. (003336013)