

**CORTIZONE 10 ITCH RELIEF MASSAGING ROLLERBALL- hydrocortisone cream
Chattem, Inc.**

Cortizone 10 Itch Relief Massaging Rollerball

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Drug Facts

Active ingredient

Purpose

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 ■ detergents ■ jewelry ■ cosmetics

■ soaps ■ seborrheic dermatitis

■ other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

Do not use

■ for the treatment of diaper rash. Consult a doctor.

■ if you are allergic to any ingredient in this product

When using this product

■ avoid contact with the eyes ■ do not use more than directed unless told to do so by a doctor

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, do not use this or any other hydrocortisone product unless you have asked a doctor

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

■ **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

Inactive ingredients

water, alcohol denat. (15%), dimethicone, caprylyl methicone, cetearyl alcohol, ceteth-20 phosphate, hydroxyethyl acrylate/sodium acryloyldimethyl taurate copolymer, glycerin, ethylhexylglycerin, aloe barbadensis leaf juice, hydroxyacetophenone, glyceryl stearate, C30-45 alkyl cetearyl dimethicone crosspolymer, isohexadecane, acrylates/C10-30 alkyl acrylate copolymer, dicetyl phosphate, aminomethyl propanol, steareth-2, steareth-21, polysorbate 60, disodium EDTA, citric acid

PRINCIPAL DISPLAY PANEL

Cortizone 10

Itch Relief

Massaging Rollerball 1.5 FL OZ (44.3 mL)



CORTIZONE 10 ITCH RELIEF MASSAGING ROLLERBALL

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41167-0338
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)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETETH-20 PHOSPHATE (UNII: 921FTA1500)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%) (UNII: 86FQE96TZ4)	
GLYCERIN (UNII: PDC6A3C0OX)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
C30-45 ALKYL CETEARYL DIMETHICONE CROSSPOLYMER (UNII: 4ZK9VP326R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
DIHEXADECYL PHOSPHATE (UNII: 2V6E5VWN99N)	
AMINOMETHYLPROPANOL (UNII: LU49E6626Q)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0338-0	1 in 1 CARTON	01/02/2023	
1		42 g in 1 BOTTLE, WITH APPLICATOR; 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	01/02/2023	

Revised: 11/2023

Chattem, Inc.