

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

Cortizone 10 Itch Relief Massaging Rollerball

Cortizone 10 Itch Relief Massaging Rollerball

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: 92RU3N3Y10)	
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: 2V6E5VN99N)	
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	

