CORTISONE 10 OVERNIGHT CREME- hydrocortisone cream Chattem, Inc. -----Cortizone 10 Overnight Creme

Cortizone 10 Overnight Relief
Drug Facts

Active ingredient

Purpose

Hydrocortisone
1%......Antiitch

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

water, glycerin, dimethicone, petrolatum, jojoba esters, cetyl alcohol, aloe barbadensis leaf juice, stearyl alcohol, distearyldimonium chloride, cetearyl alcohol, steareth-2, steareth-21, beta-glucan, melatonin, methyl gluceth-20, hydroxyacetophenone, ethylhexylglycerin, chamomilla recutita (matricaria) flower extract, tocopheryl acetate, magnesium ascorbyl phosphate, hydrolyzed jojoba esters, propylene glycol, polysorbate 60, stearamidopropyl PG-dimonium chloride phosphate, glyceryl stearate, menthyl lactate, EDTA, PPG-12/SMDI copolymer, potassium hydroxide, methylparaben, fragrance

PRINCIPAL DISPLAY PANEL

Cortizone 10 Overnight Crème Net wt 1 oz (28 g)



CORTISONE 10 OVERNIGHT CREME

hydrocortisone cream

Product Information	ION
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Product Type HUMAN OTC DRUG Item Code (Source) NDC:41167-0109

Route of Administration TOPICAL

Active Ingredient/Active Moiety

Ingredient Name
Basis of Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII: W4X0X7BPJ)
HYDROCORTISONE
1 g in 100 g

Inactive Ingredients

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Strength			

DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
STEARETH-2 (UNII: V56DFE46J5)
STEARETH-21 (UNII: 53J3F32P58)
MELATONIN (UNII: JL5DK93RCL)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
HYDROXYACETOPHENONE (UNII: G1L3HT4CMH)
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)
CHAMOMILE (UNII: FGL3685T2X)
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)
POLYSORBATE 60 (UNII: CAL22UVI4M)
STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: W6000VEI5Y)
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)
EDETIC ACID (UNII: 9G34HU7RV0)
PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
METHYLPARABEN (UNII: A2I8C7HI9T)
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)
TRANSFORMING GROWTH FACTOR BETA RECEPTOR TYPE 3 (UNII: 18YWT2KYS8)

P	Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date			
1	NDC:41167- 0109-2	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)

Revised: 11/2023 Chattem, Inc.