

**CORTISONE 10 INTENSIVE MOISTURE CREME- hydrocortisone cream  
Chattem, Inc.**

*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.*

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**Cortizone 10 Intensive Moisture Creme**

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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***

water, glycerin, petrolatum, jojoba esters, cetyl alcohol, aloe barbadensis leaf juice, stearyl alcohol, distearyldimonium chloride, cetearyl alcohol, steareth-2, steareth-21, magnesium ascorbyl phosphate, chamomilla recutita (matricaria) flower extract, hydrolyzed jojoba esters, tocopheryl acetate, niacinamide, polysorbate 60, stearamidopropyl PG-dimonium chloride phosphate, dimethicone, glyceryl stearate, hydroxyacetophenone, methyl gluceth-20, menthyl lactate, propylene glycol, ethylhexylglycerin, PPG-12/SMDI copolymer, disodium EDTA, beta-glucan (357-178)

## **PRINCIPAL DISPLAY PANEL**

### **MAXIMUM STRENGTH**

**Cortizone 10**

**INTENSIVE MOISTURE CREME**

**1% Hydrocortisone**

**Anti-Itch Creme**

**Net wt 1 oz (28 g)**



## CORTISONE 10 INTENSIVE MOISTURE CREME

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41167-0022
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>JOJOBA OIL, RANDOMIZED</b> (UNII: 7F0EV20QYL)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>DISTEARYLDIMONIUM CHLORIDE</b> (UNII: OM9573Z X3X)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	

<b>STEARETH-2</b> (UNII: V56DFE46J5)
<b>STEARETH-21</b> (UNII: 53J3F32P58)
<b>MAGNESIUM ASCORBYL PHOSPHATE</b> (UNII: 0R822556M5)
<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>HYDROLYZED JOJOBA ESTERS (ACID FORM)</b> (UNII: UDR641JW8W)
<b>ALPHA-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>NIACINAMIDE</b> (UNII: 25X5118RD4)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE</b> (UNII: W6000VEI5Y)
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O)
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)
<b>HYDROXYACETOPHENONE</b> (UNII: G1L3HT4CMH)
<b>METHYL GLUCETH-20</b> (UNII: J3QD0LD11P)
<b>MENTHYL LACTATE, (-)-</b> (UNII: 2BF9E65L7I)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)
<b>PPG-12/SMDI COPOLYMER</b> (UNII: 1BK9DDD24E)
<b>EDETATE DISODIUM ANHYDROUS</b> (UNII: 8NLQ36F6MM)
<b>TRANSFORMING GROWTH FACTOR BETA RECEPTOR TYPE 3</b> (UNII: 18YWT2KYS8)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41167-0022-0	1 in 1 CARTON	01/01/2023	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:41167-0022-5	1 in 1 CARTON	01/01/2023	
2		56 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	01/01/2023	

**Labeler** - Chattem, Inc. (003336013)