

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

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

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:41167-0022 |
| 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) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| JOJOBA OIL, RANDOMIZED (UNII: 7F0EV20QYL) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573Z X3X) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |

| |
|---|
| STEARETH-2 (UNII: V56DFE46J5) |
| STEARETH-21 (UNII: 53J3F32P58) |
| MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5) |
| CHAMOMILE (UNII: FGL3685T2X) |
| HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W) |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| NIACINAMIDE (UNII: 25X51I8RD4) |
| POLYSORBATE 60 (UNII: CAL22UVI4M) |
| STEARAMIDOPROPYL PG-DIMONIUM CHLORIDE PHOSPHATE (UNII: W6000VEI5Y) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) |
| HYDROXYACETOPHENONE (UNII: G1L3HT4CMH) |
| METHYL GLUCETH-20 (UNII: J3QD0LD11P) |
| MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I) |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) |
| ETHYLHEXYLGLYCERIN (UNII: 147D247K3P) |
| PPG-12/SMDI COPOLYMER (UNII: 1BK9DDD24E) |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |
| TRANSFORMING GROWTH FACTOR BETA RECEPTOR TYPE 3 (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 | | |
| 3 | NDC:41167-0022-6 | 2 in 1 CARTON | 01/01/2023 | |
| 3 | | 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 Drug | M017 | 01/01/2023 | |

Labeler - Chattem, Inc. (003336013)