HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone cream Chain Drug Consortium, LLC

Hydrocortisone Cream Maximum Strength - Premier Value

Drug Facts

Active ingredient

Hydrocortisone, USP 1%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:

- •eczema •insect bites •poison ivy •poison oak •poison sumac •soaps
- •jewelry •detergents •cosmetics •psoriasis •seborrheic dermatitis
- •for external genital, feminine and anal itching
- •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 external feminine itching 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 the eyes •do not begin the use of any other hydrocortisone product unless directed by a doctor
- •for external anal itching: •do not use more than directed unless directed by a doctor
- •do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

•symptoms last for more than 7 days •the condition gets worse •symptoms clear up

and occur again in a few days •rectal bleeding occurs, consult doctor promptly

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, consult a doctor For external anal itching

Adults: when practical, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product

Children under 12 years of age: consult a doctor

Other information

- Store at room temperature 59°-86°F (15°-30°C). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

cetyl alcohol, glyceryl stearate, isopropyl myristate, methylparaben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax. May contain citric acid or sodium citrate solution to adjust pH.

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday-Friday.

PRINCIPAL DISPLAY PANEL

Premier Value®

COMPARE TO THE ACTIVE INGREDIENT IN CORTIZONE • 10 8 *

MAXIMUM STRENGTH

Hydrocortisone Cream, USP 1%

ANTI-ITCH CREAM

Relieves Itches and Rashes

For the temporary relief of itching associated with minor skin irritations, inflammation and rashes

NET WT 1 OZ (28g)



HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68016-102

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|--------------------------|----------|
|-----------------|--------------------------|----------|

HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII: W4X0X7BPJ) HYDROCORTISONE

DROCORTISONE 1 g in 100 g

| Inactive Ingredients | | |
|--|----------|--|
| Ingredient Name | Strength | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | | |
| GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4) | | |
| ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS) | | |
| METHYLPARABEN (UNII: A218C7HI9T) | | |
| POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I) | | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | | |
| PROPYLPARABEN (UNII: Z8IX2SC10H) | | |
| WATER (UNII: 059QF0KO0R) | | |
| SORBIC ACID (UNII: X045WJ989B) | | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | | |
| WHITE WAX (UNII: 7G1J5DA97F) | | |

| P | Packaging | | | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | | |
| 1 | NDC:68016-102- 01 | 1 in 1 CARTON | 09/08/2006 | | | | |
| 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 | 09/08/2006 | 12/27/2024 | |
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Labeler - Chain Drug Consortium, LLC (101668460)

Revised: 3/2024 Chain Drug Consortium, LLC