

HYDROCORTISONE ANTI-ITCH- hydrocortisone cream
Universal Distribution Center LLC

Hydrocortisone Anti-Itch Cream

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

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

- eczema
- seborrheic dermatitis
- psoriasis
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- external genital, feminine and anal itching

Other uses or the use of the product for more than 7 days should be undertaken only under the advice and supervision of a doctor

Warnings

For external use only

Do not use in genital area if you have a vaginal discharge.

Consult a doctor, for the treatment of diaper rash. Ask 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: Ask a doctor

For external anal and genital itching, adults:

When practical, clean the affected area with mild soap and 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.

Other information

- Store at 20°C to 25° C (68°F to 77° F)
- Lot No. & Exp. Date: see crimp of tube

Inactive Ingredients

Purified Water, Mineral Oil, Propylene Glycol, Cetearyl Alcohol, Petrolatum, Glyceryl Stearate, Polysorbate 60, Sorbitan Stearate, Methylparaben, Propylparaben, Disodium Edta

PRINCIPAL DISPLAY PANEL

HYDROCORTISONE ANTI-ITCH CREAM

NET WT 0.5 OZ. (14 g)

New

Maximum Strength

***Compare to the active ingredients in CORTAID®**

Hydrocortisone
1% Anti-Itch Cream

MAXIMUM STRENGTH

Helps Heal Rashes

Net Wt. 0.5 oz (14g)

Drug Facts

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Hydrocortisone 1%

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Anti-Itch

Uses for the temporary relief of itching associated with minor skin irritations and rashes due to:
■ eczema ■ seborrheic dermatitis ■ psoriasis ■ insect bites ■ poison ivy, oak, sumac ■ soaps ■ detergents ■ cosmetics ■ jewelry ■ external genital, feminine and anal itching.
Other uses or the use of the product for more than 7 days should be undertaken only under the advice and supervision of a doctor.

Warnings For external use only Do not use in genital area if you have a vaginal discharge. Consult a doctor, for the treatment of diaper rash. Ask a doctor.

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Distributed By: Universal Distribution Center, 96 Distribution Boulevard, Edison, NJ 08817 www.universalbrandsusa.com
Lot No. & Exp. Date: see crimp of tube. Item#86069 Made in India

HYDROCORTISONE ANTI-ITCH

hydrocortisone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52000-022 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE | 0.01 g in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| EDETATE SODIUM (UNII: MP1J8420LU) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|----------|------------------|---|-----------------------------|---------------------------|
| 1 | NDC:52000-022-37 | 1 in 1 BOX | 12/09/2020 | |
| 1 | NDC:52000-022-36 | 14 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 | 12/09/2020 | |

Labeler - Universal Distribution Center LLC (019180459)