

HYDROCORTISONE- hydrocortisone cream
Discount Drug Mart, 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.

Discount Drug Mart Hydrocortisone 1% cream

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to:

- eczema
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- seborrheic dermatitis
- psoriasis
- 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

- if you are allergic to any of the ingredients
- in the genital area if you have a vaginal discharge. Consult a doctor
- for the treatment 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 finders or any mechanical devices 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 day, 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 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 soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years age. Ask a doctor

Other information

- store at 20° to 25°C (63° to 77°F)
- see end of carton or tube crimp for lot number and expiration date

Butylated hydroxytoluene, Cetyl alcohol, Glycerin, Glyceryl monostearate, Isopropyl myristate, Methylparaben, Propylparaben, Purified water, Squalane, Stearic acid

Hydrocortisone





HYDROCORTISONE

hydrocortisone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:53943-984 |
| 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 |
|--|----------|
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| SQUALANE (UNII: GW89575KF9) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:53943-984-01 | 1 in 1 BOX | 10/30/2015 | |
| 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 not final | part348 | 10/30/2015 | |

Labeler - Discount Drug Mart, Inc. (047741335)

Revised: 2/2023

Discount Drug Mart, Inc.