HYDROCORTISONE- hydrocortisone cream cream McKesson

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.

Hydrocortisone Cream

Drug Facts

Hydrocortisone Cream 1%

Active Ingredients (in each gram)

Hydrocortisone USP 10 mg

Purpose

Antipruritic (Anti Itch)

Indications:

For the temporary relief of itching associated with minor skin irritation and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis scrapes
For the temporary relief of 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

- Avoid contact with eyes
- Do not exceed the recommended daily dosage unless directed by a doctor
- Do no use for treatment of diaper rash
- In case of bleeding, consult a doctor promptly

Consult a doctor:

- Before use if you have a vaginal discharge (for external feminine itching)
- For external itching, do not exceed the recommended daily dosage or if bleeding occurs
- If condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days discontinue use of this product

When using this product:

 Do not put this product into rectum by using fingers or any mechanical device or applicator

Do Not Use:

With any other Hydrocortisone product unless you have consulted a doctor

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away 1-800-222-1222

Directions:

- For adults and children 2 years of age and older: apply externally to affected area not more than 3 to 4 times daily.
- Children under 2 years of age: do not use, consult a doctor
- Adults for external anal itching when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly, or by patting or blotting with appropriate cleansing pad. Gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product.
- Children under 12 years or age; for external anal itching, consult a doctor.

Other Information:

- Store at controlled room temperature 59* to 86*F (15* to 30*C)
- Avoid excessive heat and humidity
- Tamper Evident. Do not use if packet is torn, cut or opened

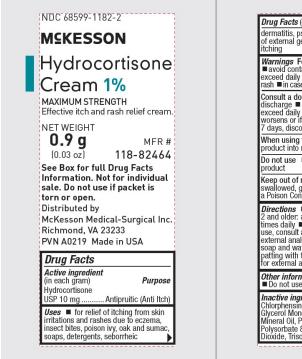
Inactive Ingredients:

Benzoic acid, chlorphenesin, citric acid, glycerin, glyceryl monostearate, methylparaben, mineral oil, petrolatum, phenoxyethanol, polysorbate 80, purified water, titanium dioxide, trisodium citrate.

Ouestions? Call 1-800-777-4908

NDC 68599-1182-2 Hydrocortisone Cream 1% Maximum Strength Effective itch and rash relief cream. NET WEIGHT 0.9 g (0.03 oz)

MFR # 118-82464





NDC 68599-1182-2 McKesson Hydrocortisone Cream 1% Maximum Strength NET WEIGHT 0.9 g (0.03 oz) 144 PACKS PER BOX MFR # 118-82464



NDC 68599-1182-2 McKesson Hydrocortisone Cream 1% Maximum Strength NET WEIGHT 0.9 g (0.03 oz) 144 PACKS PER BOX 12 BOXES PER CASE MFR # 118-82464 NDC 68599-1182-2

118-82464

MSKESSON

Hydrocortisone Cream 1%

MAXIMUM STRENGTH

0.9 g

144 | 12

PACKS BOXES

PER POY

Store at 59-86°F (15-30°C). Avoid excessive heat and humidity. Not made with natural rubber latex.

Distributed by McKesson Medical-Surgical Inc. Richmond, VA 23233

PVN A0219 Made in USA

LOT EXP 6 12479 24350 7

118-82464

MFR#

HYDROCORTISONE

hydrocortisone cream cream

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:68599-1182

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 |
|--|----------|
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| POLYSORBATE 80 (UNII: 60ZP39ZG8H) | |
| TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| CLYCERYL MONOCTEARATE (INNI), 2200 HOVYEA) | |

GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)

METHYLPARABEN (UNII: A2I8C7HI9T)

MINERAL OIL (UNII: T5L8T28FGP)

PHENOXYETHANOL (UNII: HIE492ZZ3T)

BENZOIC ACID (UNII: 85KN0B0MIM)

WATER (UNII: 059QF0KO0R)

TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

| CHLORPHENESIN (UNII: 1670DAL4SZ) | |
|----------------------------------|--|
| PETROLATUM (UNII: 4T6H12BN9U) | |

| Packaging | | | | | |
|---------------------|---|-------------------------|-----------------------|--|--|
| # Item Co | de Package Description | Marketing Start Date | Marketing End Date | | |
| 1 NDC:68599- | 0.9 g in 1 PACKET; Type 0: Not a Combinatio Product | on 03/14/2019 | | | |

| Marketing Information | | | | | |
|-------------------------|---|-------------------------|-----------------------|--|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | | |
| OTC monograph not final | part348 | 03/13/2019 | 07/01/2024 | | |
| | | | | | |

Labeler - McKesson (023904428)

| Establishment | | | | | |
|------------------------|---------|-----------|----------------------------|--|--|
| Name | Address | ID/FEI | Business Operations | | |
| Ultra Seal Corporation | | 085752004 | pack(68599-1182) | | |

Revised: 1/2023 McKesson