

**FAMILY WELLNESS MAX STRENGTH 1 HYDROCORTISONE CREAM-
hydrocortisone cream
Family Dollar Stores, 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.

Family Wellness Max Strength 1% Hydrocortisone Cream

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 be under 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 persists 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 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 room temperature 68°-77°F (20°-25°C).
- tamper-evident: do not use if foil seal is broken or missing.

Inactive ingredients

aloe barbadensis leaf juice, cetyl alcohol, disodium EDTA, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, purified water, sorbitan monostearate

Questions?

1-800-639-3803 Weekdays 9 AM to 4 PM EST

Package Labeling:



- Inflammation
- Rashes

- Insect Bites
- Eczema

- Psoriasis

LOT:
EXP:

FAMILY
Wellness

COMPARE TO THE ACTIVE INGREDIENTS OF CORTIZONE-10®*

MAXIMUM STRENGTH

1% HYDROCORTISONE CREAM

WITH
ALOE

NET WT 1 OZ (28 g)

CREAM

NDC 55319-XXX-XX

SKU 910321

*This product is not manufactured or distributed by Chatterm, Inc., distributor of Cortizone-10®.

DISTRIBUTED BY:
MIDWOOD BRANDS, LLC
500 VOLVO PARKWAY,
CHESAPEAKE, VA 23320 USA

MADE IN CHINA



NOT 100% SATISFIED?
Return package and unused product within 30 days to any Family Dollar store for a refund (with receipt) or exchange.



Drug Facts

Active ingredients 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
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Warnings For external use only.

- Do not use**
- in the genital area if you have a vaginal discharge. Consult a doctor.
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When using this product

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- 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 persists for more than 7 days or clear up and occur again within a few days, and do not

Drug Facts (continued)

- 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:
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 - 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 room temperature 66°-77°F (20°-25°C).
■ tamper-evident: do not use if foil seal is broken or missing.

Inactive ingredients aloe barbadensis leaf juice, cetyl alcohol, disodium EDTA, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, purified water, sorbitan monostearate

Questions? 1-800-639-3803 Weekdays 9 AM to 4 PM EST

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or 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 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 room temperature 68° - 77° F (20° - 25° C) **Inactive ingredients** aloe barbadensis leaf juice, cetyl alcohol, disodium EDTA, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, purified water, sorbitan monostearate

Questions? 1-800-639-3803 Weekdays 9 AM to 4 PM EST **DISTRIBUTED BY: MIDWOOD BRANDS, LLC**
500 VOLVO PARKWAY, CHESAPEAKE, VA 23320 USA
*This product is not manufactured or distributed by Chattem, Inc., distributor of Cortizone-10®. **MADE IN CHINA**

FAMILY WELLNESS MAX STRENGTH 1 HYDROCORTISONE CREAM

hydrocortisone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:55319-982 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|--------------|
| HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE | 10 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| PETROLATUM (UNII: 4T6H12BN9U) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| WATER (UNII: 059QF0KO0R) | |
| SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:55319-982-00 | 1 in 1 BOX | 01/01/2024 | |
| 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 | 01/01/2024 | |

Labeler - Family Dollar Stores, Inc (024472631)

Revised: 8/2023

Family Dollar Stores, Inc