

## **HYDROCORTISONE WITH ALOE MAXIMUM STRENGTH- hydrocortisone cream Major Pharmaceuticals**

*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.*

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### **Hydrocortisone Cream with Aloe Maximum Strength - Major**

#### ***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***

aloe vera concentrate, 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?**

**1-888-838-2872 between 9 am and 5 pm ET, Monday-Friday.**

**PRINCIPAL DISPLAY PANEL**

Major®

NDC 0904-7623-31

Maximum Strength

Hydrocortisone • 10

Hydrocortisone Cream, USP 1%

antipruritic (anti-itch) cream With Aloe

Temporary Relief of Itching and Rashes Due To:

- Insect Bites • Eczema • Soaps
- Poison Ivy, Oak, Sumac • Seborrheic Dermatitis • Cosmetics
- Psoriasis • Jewelry • Detergents

Compare to the Active Ingredient in Cortizone • 10®\*

NET WT 1 OZ (28 g)



# HYDROCORTISONE WITH ALOE MAXIMUM STRENGTH

hydrocortisone cream

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:0904-7623 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| Ingredient Name   | Basis of Strength | Strength     |
|---|-------------------|--------------|
| <b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) | HYDROCORTISONE    | 1 g in 100 g |

**Inactive Ingredients**

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)        |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)         |          |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4) |          |
| <b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)   |          |
| <b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)         |          |
| <b>POLYOXYL 40 STEARATE</b> (UNII: 13A4J4NH9I)  |          |
| <b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)        |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |          |
| <b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)         |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |          |
| <b>SORBIC ACID</b> (UNII: X045VJ989B)           |          |
| <b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X) |          |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)       |          |
| <b>WHITE WAX</b> (UNII: 7G1J5DA97F)             |          |

**Packaging**

| # | Item Code        | Package Description                               | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:0904-7623-31 | 1 in 1 CARTON                                     | 04/21/2009           |                    |
| 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                                  | 04/21/2009           | 01/31/2025         |

**Labeler** - Major Pharmaceuticals (191427277)

Revised: 10/2022

Major Pharmaceuticals