

**HYDROCORTISONE - hydrocortisone cream**  
**Navarro Discount Pharmacies,LLC**

*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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**Drug Facts**

**Active Ingredient**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses**

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

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

Other uses of this product: ask a doctor

**Warnings**

For external use only

**Do not use**

- in or near the eyes
- by putting directly into the rectum by using fingers or any mechanical device or applicator
- for external feminine itching if you have a vaginal discharge
- for diaper rash; ask a doctor

**Ask a doctor or pharmacist before use if you are**

using any other hydrocortisone product

**When using this product**

for external anal itching, do not exceed recommended daily dosage unless directed by a doctor

**Stop use and ask a doctor if**

- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- rectal bleeding occurs

## Keep out of reach of children

If swallowed, get medical help or contact a Poison Control right away.

## Directions

- apply to affected area not more than 3 to 4 times daily
- for external anal itching: when practical, clean 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 2 years, or children under 12 years with external anal itching: do not use, ask a doctor

## Other information

- store at room temperature, protect from freezing

Cetyl alcohol, Butylated hydroxytoluene, Glycerin, Glyceryl monostearate, Isopropyl myristate, Myristoyl/palmitoyl/oxostearamide/arachamide MEA, Methylparaben, PEG-15 glyceryl stearate, Squalane, Stearic acid, Propylparaben, Purified water

Hydrocortisone



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|--|--|--|
| <p><b>Drug Facts</b></p> <p><b>Active ingredient</b><br/>Hydrocortisone 1.0%</p> <p><b>Purpose</b><br/>Anti-itch</p>   |  | <p><b>Uses</b><br/>temporarily relieves itching associated with minor skin irritation, irritation and rashes due to:<br/>eczema ■ psoriasis ■ seboremic dermatitis<br/>poison ivy, oak, sumac ■ insect bites<br/>soaps and detergents ■ cosmetics<br/>jewelry ■ external feminine and anal itching<br/>Other uses of this product: ask a doctor.</p> |
| <p><b>Warnings</b><br/>For external use only</p> <p><b>Do not use</b><br/>■ in or near the eyes<br/>■ by putting directly into the rectum by using fingers or any mechanical device or applicator<br/>■ for external female itching if you have a vaginal discharge<br/>■ for diaper rash; ask a doctor.</p>   |  | <p><b>Stop use and ask a doctor if</b><br/>■ condition worsens or does not improve within 7 days<br/>■ symptoms clear up and return within a few days<br/>■ rectal bleeding occurs</p>   |
| <p><b>Directions</b><br/>■ apply to affected area not more than 3 to 4 times daily<br/>■ for external anal itching, when practical, clean area with mild soap and warm water, nose thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of the product<br/>■ children under 2 years, or children under 12 years with external anal itching, do not use, ask a doctor.</p> |  | <p><b>Ask a doctor or pharmacist before use if you are</b><br/>using any other hydrocortisone product<br/><b>When using this product</b> for external anal itching, do not exceed recommended daily dosage unless directed by a doctor.</p>  |
| <p><b>Other information</b><br/>■ store at room temperature, protect from freezing</p>   |  | <p><b>Keep out of reach of children.</b><br/>If swallowed, get medical help or contact a Poison Control Center right away.</p>   |
| <p><b>Drug Facts (continued)</b></p> <p><b>Inactive ingredients</b><br/>cetyl alcohol, butylated hydroxytoluene, glycerin, glyceryl monostearate, isopropyl myristate, methylparaben, PEG-15 glyceryl stearate, squelene, stearic acid, propylparaben, purified water.</p> <p>*This product is not manufactured or distributed by Pharmacia Consumer Healthcare, owner of the registered trademark, Cortaid.</p>         |  | <p><b>Exclusively distributed by:</b><br/><b>MAGELAN</b><br/>DISTRIBUTION SOLUTIONS<br/>Medley, Florida 33178</p> <p>Made in Korea</p>   |



## HYDROCORTISONE

hydrocortisone cream

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:59970-041 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

### Active Ingredient/Active Moiety

| Ingredient Name  | Basis of Strength | Strength     |
|--|-------------------|--------------|
| Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ) | 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:59970-041-01 | 1 in 1 BOX          |                      |                    |
| 1 |                  | 28 g in 1 TUBE      |                      |                    |

**Marketing Information**

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part348                                  | 08/01/2012           |                    |

**Labeler** - Navarro Discount Pharmacies,LLC (094930963)

Revised: 8/2012

Navarro Discount Pharmacies,LLC