

## **HYDROCORTISONE- hydrocortisone cream**

### **Kroger Company**

*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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### **Kroger Co. Hydrocortisone Cream, USP 1% Drug Facts**

#### **Active ingredient**

Hydrocortisone 1%

#### **Purpose**

Anti-itch

#### **Uses**

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- insect bites
- poison ivy, oak, or 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**

- 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 persist 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 (1-800-222-1222).

**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, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a 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 20-25°C (68-77°F)

**Inactive ingredients**

water, cetearyl alcohol, cetareth-20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, aloe barbadensis leaf juice

**Questions or comments?**

**1-800-632-6900**

**Principal Display Panel**

COMPARE TO active ingredient of CORTAID® MAXIMUM STRENGTH CREAM See side panel

Hydrocortisone Cream, USP 1%

Maximum Strength Anti-Itch Cream

Helps skin appear visibly healthier from:

Redness & dryness

Flaking & scaling

Cracking

NET WT 1 OZ (28g)

Code Area

COMPARE TO active ingredient of CORTAID® MAXIMUM STRENGTH CREAM †See side panel

NDC 30142-541-64



# Hydrocortisone Cream, USP 1%

**Maximum Strength Anti-Itch Cream**

Helps skin appear visibly healthier from:  
Redness & dryness  
Flaking & scaling  
Cracking

DISTRIBUTED BY  
THE KROGER CO.  
CINCINNATI, OHIO  
45202

QUALITY GUARANTEE  
[www.kroger.com](http://www.kroger.com)

†THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY VALEANT PHARMACEUTICALS NORTH AMERICA LLC, DISTRIBUTOR OF CORTAID® MAXIMUM STRENGTH CREAM.



NET WT 1 OZ (28g)



### Drug Facts

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Hydrocortisone 1%.....Anti-itch

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#### Warnings

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##### When using this product

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- 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 persist 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 (1-800-222-1222).

### Drug Facts (continued)

#### Directions

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#### Questions or comments?

1-800-632-6900

54164 45 C4

Code Area



# HYDROCORTISONE

hydrocortisone cream

## Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-541
Route of Administration	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
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISO STEARYL NEOPENTANOATE (UNII: 411THY156Q)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

## Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-541-64	1 in 1 CARTON	04/05/2017	
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	04/05/2017	

