

## **HYDROCORTISONE- hydrocortisone cream**

**Kareway Product, 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.*

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### **Soundbody Hydrocortisone**

#### **Active Ingredient**

Hydrocortisone 1%

#### **Purpose**

Anti-itch

#### **Uses**

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

- eczema
- insect bites
- poison ivy, oak, 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. Ask 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.

**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: Ask a doctor
- for external anal and genital itching, adults:
- when practical, clean the affected area with mild soap and 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 to 25 °C (68 to 77 °F)
- see end of carton or tube crimp for lot number and expiration date

butylated hydroxytoluene, carbomer 940, cetyl alcohol, ethylparaben, glycerin, glyceryl stearate, propylene glycol, sodium lauryl sulfate, stearic acid, trolamine, water

Hydrocortisone



COMPARE TO THE  
ACTIVE INGREDIENT IN  
**CORTIZONE-10®**

Relieves itches, rashes and skin irritations:

- eczema • poison ivy, oak, and sumac
- psoriasis • dermatitis • insect bites

NDC 67510-0632-1

**MAXIMUM STRENGTH**

# 1% Hydrocortisone

NET WT. 1 OZ (28.3g)

**Anti-Itch Cream**

Relieves itches, rashes and skin irritations:

- eczema • poison ivy, oak, and sumac
- psoriasis • dermatitis • insect bites



**MAXIMUM STRENGTH**

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NET WT. 1 OZ (28.3g)

**Anti-Itch Cream**



**MAXIMUM STRENGTH**

# 1% Hydrocortisone

**Anti-Itch Cream**



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LOT & EXP.

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each gram)</b> Hydrocortisone 1% (10 mg/g)</p> <p><b>Purpose</b> Anti-Itch</p> <p><b>Directions</b> 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: ask a doctor • for external anal and genital itching, adults: • when practical, clean the affected area with mild soap and 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</p> <p><b>Other information</b> • store at 20° to 25°C (68° to 77°F) • see end of carton or tube crimp for lot number and expiration date <b>Inactive ingredients</b> butylated hydroxytoluene, carbomer 940, purified water, sodium lauryl sulfate, stearic acid, tocopherol, cetyl alcohol, ethylhexylglycerin, glyceryl stearate, propylene glycol</p> <p><b>Questions or Comments?</b> 1-800-983-0065</p> <p><small>This product is not manufactured or distributed by Cadbury, Inc. Distributed by: Keweenaw Hills Dr. Company, CA 90220 2550 S. Dominguez Hills Dr. Company, CA 90220 VH100694 MADE IN CHINA ITM006942</small></p>	<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each gram)</b> Hydrocortisone 1% (10 mg/g)</p> <p><b>Purpose</b> Anti-Itch</p> <p><b>Directions</b> For itching of skin irritation, inflammation, and rashes due to: • eczema • insect bites • poison ivy, oak, or sumac • soaps • detergents • cosmetics • jewelry • sebaceous dermatitis • psoriasis • temporally relieves external anal and genital itching • other uses of this product should only be under the advice and supervision of a doctor</p> <p><b>Warnings</b> For external use only.</p> <p><b>Do not use</b> • in the genital area if you have a vaginal discharge. Consult a doctor. • for the treatment of diaper rash. Ask a doctor.</p> <p><b>When using this product</b> • 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</p> <p><b>Stop use and ask a doctor if</b> • 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</p>
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**1% Hydrocortisone**  
MAXIMUM STRENGTH  
Anti-Itch Cream



HYDROCORTISONE

hydrocortisone cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67510-0632
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
TROLAMINE (UNII: 9O3K93S3TK)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
ETHYL PARABEN (UNII: 14255EXE39)	
GLYCERYL 1-STEARATE (UNII: 258491E1RZ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
WATER (UNII: 059QF0KO0R)	

## Packaging

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:67510-0632-1	1 in 1 BOX	12/12/2013	
1		28.3 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	12/12/2013	

**Labeler** - Kareway Product, Inc. (121840057)