

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.

Pure-Aid Hydrocortisone 1% Cream

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 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

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

MAXIMUM STRENGTH

FAST RELIEF

✓ **Itching** ✓ **Redness**

Anti-Itch Cream for Skin Irritations

NDC No. 68374-002-04
Pure-Aid™

Compare to maximum strength Cortaid® active ingredient*

MAXIMUM STRENGTH

KAREWAY

MAXIMUM STRENGTH **1% Cream**

Hydrocortisone

Relieves Itching and Redness Fast!

NET 1 oz(28.3g)

1% Cream

Hydrocortisone

Relieves Itching and Redness Fast!

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LOT & EXP.

<p>Drug Facts</p> <p>Active Ingredient Hydrocortisone 1.0%.....Anti-itch</p> <p>Purpose Anti-itch</p> <p>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control.</p> <p>Drug Facts(continued)</p>	<p>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</p> <p>Warnings Other uses of this product: ask a doctor ■ jewelry ■ external feminine and anal itching ■ insect bites ■ soaps and detergents ■ cosmetics ■ psoriasis ■ seborrheic dermatitis ■ poison ivy, oak, sumac ■ insect bites ■ soaps and detergents ■ cosmetics</p> <p>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</p> <p>Ask a doctor or pharmacist before use if you are using any other hydrocortisone product</p> <p>When using this product for external anal itching, do not exceed recommended daily dosage unless directed by a doctor</p> <p>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</p> <p>Exclusively distributed by: Kareway Product Inc. Pharmacal Consumer Healthcare, owner of the registered trademark Cortaid® Heartlake, CA 90220</p> <p>Made in Korea</p>
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Directions
■ apply to affected area not more than 3 to 4 times daily 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

Other information
■ store at room temperature, protect from freezing
■ store at room temperature, protect from freezing

Inactive ingredients Carboly alcohol, Butylated hydroxytoluene, Glyceryl monostearate, Myristoyl myristate, Myristoyl palmitoyl oxostearamide arachamide MEA, Methylparaben, Propylparaben, Purified water

Warnings
with external anal itching; do not use, ask a doctor
■ children under 2 years, or children under 12 years

Other uses of this product: ask a doctor

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1% Cream
Hydrocortisone
Relieves Itching and Redness Fast!

Hydrocortisone

Relieves Itching and Redness Fast!

KAREWAY

HYDROCORTISONE
hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67510-0065
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 h 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:67510-0065-1	1 in 1 BOX	08/10/2011	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:67510-0065-5	1 in 1 BOX	08/10/2011	
2		14 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	08/10/2011	

Labeler - Kareway Product, Inc. (121840057)