

**CAREALL HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone cream**  
**New World Imports, 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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**Drug Facts**

**Active Ingredient**

Hydrocortisone 1%

**Purpose**

Anti-Itch

**Keep out of reach of Children**

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

**Uses**

Temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:

eczema, psoriasis, poison ivy, poison oak, poison sumac, insect bites, detergents, jewelry, seborrheic dermatitis, soaps, external itching 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 the treatment of diaper rash. Ask a doctor

In the genital if you have a vaginal discharge. Consult a doctor

**When using this product:**

Avoid contact with the eyes

Do not use more than directed unless told to do so 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:**

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

## 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 do not use. Ask a doctor.

### For external anal and genital itching, adults:

- 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 with external anal itching: ask a doctor.

Cetamacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Edetate Disodium, Liquid Paraffin, Propylene Glycol, Purified Water, White Soft Paraffin

**CAREALL** 

# Anti-Itch Cream

**Effective Itch & Rash Relief for:**

- Eczema • Insect Bites • Poison Ivy, Oak, & Sumac
- Psoriasis • Seborrheic Dermatitis • & More

**Hydrocortisone Cream 1%**  
MAXIMUM STRENGTH

Fast Relief of Itching and Redness

**CAREALL**

**Hydrocortisone Cream 1%**  
MAXIMUM STRENGTH

Fast Relief of Itching and Redness

# Hydrocortisone Cream 1%

**MAXIMUM STRENGTH**

Made in India NDC # 51824-050-01 GUJDRUGS/G/28/1551

Distributed by: CareAll Products, 160 Athens Way, Nashville, TN 37228

<b>Drug Facts</b>	<b>Active Ingredient</b> Hydrocortisone 1% .....Anti-itch	<b>Purpose</b> Uses temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: ■ eczema ■ psoriasis ■ poison ivy, poison oak, poison sumac ■ insect bites ■ detergents ■ jewelry ■ seborrheic dermatitis ■ soaps ■ external genital and anal itching ■ other uses of this product should be only under the advice and supervision of a doctor.
<b>Drug Facts</b>	<b>Warnings</b> For external use only.	<b>Do not use</b> ■ for the treatment of diaper rash. Ask a doctor. ■ in the genital area if you have vaginal discharge. Consult a doctor.
<b>Drug Facts</b>	<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	
<b>Drug Facts</b>	<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 of age: Do not use, ask a doctor. for external anal and genital itching, adults: ■ when practical, clean 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	
<b>Drug Facts</b>	<b>Other information</b> ■ Store between 15° to 30°C (59° to 86°F) Lot No. & Exp. Date: See box or crimp of tube.	
<b>Drug Facts</b>	<b>Inactive Ingredients</b> Glycol, Purified Water, White Soft Paraffin Cetomacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Liquid Paraffin, Propylene	
<b>Drug Facts</b>	<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 <b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center right away	
<b>Drug Facts</b>	<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 of age: Do not use, ask a doctor. for external anal and genital itching, adults: ■ when practical, clean 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	
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## CAREALL HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51824-050
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone Acetate (UNII: 3X7931PO74) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone Acetate	1 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
Propylene Glycol (UNII: 6DC9Q167V3)	
Petrolatum (UNII: 4T6H12BN9U)	
Mineral Oil (UNII: T5L8T28FGP)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
CETETH-20 (UNII: I835H2IHHX)	

**Chlorocresol** (UNII: 36W5307109)

**Water** (UNII: 059QF0K00R)

### Product Characteristics

<b>Color</b>	white (White Cream)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51824-050-01	28 g in 1 TUBE; Type 0: Not a Combination Product	04/27/2016	
2	NDC:51824-050-14	144 in 1 CONTAINER	05/01/2022	
2	NDC:51824-050-09	.9 g in 1 PACKET; 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	03/11/2016	

**Labeler** - New World Imports, Inc (075372276)

Revised: 1/2022

New World Imports, Inc