

CAREALL HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone cream
New World Imports, Inc

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

The image shows the packaging for CAREALL products. The top section is blue with the CAREALL logo (a blue cross in a square) and the text "CAREALL®". Below this is a white cloud-like shape. The main title "Anti-Itch Cream" is in large white letters. Below this, in a lighter blue box, is the text "Effective Itch & Rash Relief for:" followed by a list of conditions: "Eczema • Insect Bites • Poison Ivy, Oak, & Sumac • Psoriasis • Seborrheic Dermatitis • & More". The bottom section is also blue and features the text "Hydrocortisone Cream 1%" in large white letters, with "MAXIMUM STRENGTH" in yellow below it. To the right of this text is the phrase "Fast Relief of Itching and Redness". The CAREALL logo is also present above the "Hydrocortisone Cream 1%" text. The right side of the packaging is red with a white grid pattern. At the bottom right, it says "NET WT. 1 OZ (28g)".

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

NET WT. 1 OZ (28g)

Hydrocortisone Cream 1%

MAXIMUM STRENGTH



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

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

Drug Facts	
Active Ingredient	Hydrocortisone 1% Anti-itch
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
Warnings	For external use only. Do not use ■ for the treatment of diaper rash. Ask a doctor. ■ in the genital area if you have vaginal discharge. 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
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: ■ 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
Other information	■ Store between 15° to 30°C (59° to 86°F) Lot No. & Exp. Date: See box or crimp of tube.
Inactive Ingredients	Cetomacrogol 1000, Cetostearyl Alcohol, Chlorocresol, Liquid Paraffin, Propylene Glycol, Purified Water, White Soft Paraffin
Drug Facts (continued)	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

CAREALL HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51824-050
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
Hydrocortisone Acetate (UNII: 3X7931PO74) (Hydrocortisone - UNII:VM4X0X7BPJ)		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: 36W53O7109)			
Water (UNII: 059QF0K00R)			

Product Characteristics

Color	white (White Cream)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

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 Drug	M017	03/11/2016	

Labeler - New World Imports, Inc (075372276)

Revised: 10/2023

New World Imports, Inc