

HYDROCORTISONE ULTRA STRENGTH- hydrocortisone cream
Personal Care Products, 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.

Active Ingredient

Drug Facts

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 right away.

Uses

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

- eczema
- insect bites
- cosmetics
- psoriasis
- detergents
- soaps
- poison ivy, oak
- sumac
- jewelry
- seborrheic dermatitis
- 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

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

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, 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 59° and 86° F (15° and 30° C)
- do not use if seal on tube is punctured or missing

Inactive ingredients

aloe vera gel, celeareth-20, cetyl alcohol, cetyl palitate, glycerin, isopropyl myristate, isodecyl neopentanoate, methyl paraben, purified water

Product Label

DRUGSTORE-Rx

SMART WELLNESS

Ultra Strength

Hydrocortisone Cream

Fast Itch and Rash relief

Helps relieve

- Eczema
- Seborrheic dermatitis
- Psoriasis
- Poison ivy
- Poison oak
- Poison sumac
- Insect bites and more

NET WT. 0.5 OZ. (14 g)

Distributed by: PERSONAL CARE PRODUCTS, LLC Troy, Michigan 48084 U.S.A.

Code No.:MH/DRUGS/KD-313 Made in India

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Hydrocortisone
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■ temporarily relieves external anal and genital itching ■ other uses of this product should only be under the advice and supervision of a doctor

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Drug Facts (continued)

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

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

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

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, 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

Drug Facts (continued)

Other Information ■ store between 59° and 86° F (15° and 30° C) ■ do not use if seal on tube is punctured or missing

Inactive ingredients aloe vera gel, celebreth-20, cetyl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isodecyl neopentanoate, methyl paraben, purified water.



HYDROCORTISONE ULTRA STRENGTH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:29500-2439
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	140 mg in 14 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
ISODECYL NEOPENTANOATE (UNII: W60VYE24XC)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:29500-2439-1	14 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/10/2013	

Labeler - Personal Care Products, Inc. (966155082)

Registrant - Personal Care Products, Inc. (966155082)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd.		916837425	manufacture(29500-2439)

Revised: 7/2013

Personal Care Products, Inc.