

HYDROCORTISONE ANTI-ITCH- hydrocortisone cream
Anicare Pharmaceuticals Pvt. Ltd

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.

Hydrocortisone Anti-Itch Cream

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations and rashes due to:

- eczema
- seborrheic dermatitis
- psoriasis
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- external genital, feminine and anal itching

Other uses or the use of the product for more than 7 days should be undertaken only under the advice and supervision of a doctor

Warnings

For external use only

Do not use in 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°C to 25° C (68°F to 77° F)
- Lot No. & Exp. Date: see crimp of tube

Inactive Ingredients

Purified Water, Mineral Oil, Propylene Glycol, Cetearyl Alcohol, Petrolatum, Glyceryl Stearate, Polysorbate 60, Sorbitan Stearate, Methylparaben, Propylparaben, Disodium Edta

PRINCIPAL DISPLAY PANEL

HYDROCORTISONE ANTI-ITCH CREAM

NET WT 0.5 OZ. (14 g)

Drug Facts

Active Ingredients
Hydrocortisone - 1%
Purpose
Anti-Itch

Uses for the temporary relief of itching associated with minor skin irritations and rashes due to:
■eczema ■seborrheic dermatitis ■psoriasis ■insect bites ■poison ivy, oak, sumac ■soaps ■detergents ■cosmetics ■jewelry ■external genital, feminine and anal itching.
Other uses or the use of the product for more than 7 days should be undertaken only under the advice and supervision of a doctor.

Warnings For external use only Do not use in 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:
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Other information ■Store at 20° to 25 C(68° - 77°F)

Inactive ingredients Purified Water, Mineral oil, Propylene Glycol, Cetearyl Alcohol, Petrolatum, Glyceryl Stearate, Polysorbate 60, Sorbitan Stearate, Methylparaben, Propylparaben, Disodium Edta.
Distributed By: Universal Distribution Center, 96 Distribution Boulevard, Edison, NJ 08817 www.universalbrandsusa.com
Lot No. & Exp. Date: see crimp of tube. Item#86069 Made in India

HYDROCORTISONE ANTI-ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47046-157
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE SODIUM (UNII: MP1J8420LU)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47046-157-02	1 in 1 BOX	12/09/2020	
1	NDC:47046-157-01	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	12/09/2020	

Labeler - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)**Establishment**

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(47046-157)

Revised: 12/2020

Anicare Pharmaceuticals Pvt. Ltd