

HYDROCORTISONE ANTI-ITCH- hydrocortisone cream
Universal Distribution Center LLC

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)

New

Maximum Strength

***Compare to the active ingredients in CORTAID®**

U Hydrocortisone 1% Anti-Itch Cream

Helps Heal Rashes

Net Wt. 0.5 oz (14g)

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:
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° 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:52000-022
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	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: 2DMT128M1S)	
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:52000-022-39	1 in 1 BOX	12/09/2020	
1	NDC:52000-022-38	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 Drug	M016	12/09/2020	

Labeler - Universal Distribution Center LLC (019180459)

Registrant - Sawy Care And Cosmetics Pvt. Ltd. (915039748)

Establishment

Name	Address	ID/FEI	Business Operations
Savvy Care & Cosmetics Pvt. Ltd.		915039748	manufacture(52000-022)

Revised: 5/2024

Universal Distribution Center LLC