

ANTI-ITCH- hydrocortisone cream
Medline Industries, LP

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.

091 Curad Hydrocortisone 1% Cream Anti-itch

Active ingredient (in each gram)

Hydrocortisone 1%, USP

Purpose

Antipruritic (Anti Itch)

Uses

- for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis, scrapes
- for external genital, feminine and anal itching
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

- **for external use only**
- avoid contact with eyes

Do not use and consult a doctor

- for the treatment of diaper rash
- if you have a vaginal discharge
- If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.

Do not exceed the recommended daily dosage unless directed by the doctor. In case of bleeding, consult a physician promptly. Do not put this product into the rectum by using fingers or any mechanical device or applicator.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

- For 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, consult a doctor.

For external anal itching,

- Adults: When practical, cleanse 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 application of this product.
- Children under 12 years of age: consult a doctor.

Other information

- Store at controlled room temperature 68°-77° F (20°-25° C).
- Use only if package is intact.

Inactive ingredients

cetostearyl alcohol, glyceryl monostearate SE, kathon CG, propylene glycol, purified water, stearic acid, trolamine, white petrolatum.

Manufacturing Information

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in India

www.curad.com

1-800-633-5463

REF: CUR015431

V2 RA23GZP

Package Label

Drug Facts	
Active ingredient (in each gram) Hydrocortisone 1%, USP.....	Purpose Antipruritic (Anti-Itch)
Uses ■ for the temporary relief of itching associated with minor skin irritations and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, psoriasis ■ for external genital, feminine, and anal itching ■ other uses of this product should be only under the advice and supervision of a doctor	
Warnings ■ For external use only ■ avoid contact with eyes	
Do not use and consult a doctor ■ for the treatment of diaper rash ■ if you have a vaginal discharge ■ if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.	
Do not exceed the recommended daily dosage unless directed by the doctor. In case of bleeding, consult a physician promptly. Do not put this product into the rectum by using fingers or any mechanical device or applicator.	

Drug Facts (continued)	
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Directions ■ For 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, consult a doctor.	
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Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093 USA.
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REF CUR015431



NDC: 53329-091-01



HYDROCORTISONE 1% CREAM ANTI-ITCH

1 TUBE

Not made with natural rubber latex.

NET WT. 1 oz (28.4 g)

ANTI-ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53329-091
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
WHITE PETROLATUM (UNII: B6E5W8RQJ4)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-091-01	1 in 1 BOX	03/01/2010	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:53329-091-91	48 in 1 CARTON	03/01/2010	
2	NDC:53329-091-90	1.5 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:53329-091-96	144 in 1 CASE	03/01/2010	
3		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:53329-091-90	1.5 g in 1 PACKET; Type 0: Not a Combination Product	03/01/2010	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	03/01/2010	

Labeler - Medline Industries, LP (025460908)**Registrant** - Medline Industries, LP (025460908)

Revised: 8/2023

Medline Industries, LP