

HYDROCORTISONE WITH ALOE - hydrocortisone cream
Encube Ethicals, Inc.

Hydrocortisone Cream USP, 1% with Aloe - SPL

ACTIVE INGREDIENT(S)

Hydrocortisone USP, 1%

PURPOSE

Anti-itch

USE(S)

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to
 - eczema ■ psoriasis ■ insect bites ■ poison ivy, oak sumac
 - detergents ■ jewelry ■ cosmetics ■ soaps ■ seborrheic dermatitis
- temporarily relieves external anal and genital 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

- 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 the eyes
- do not use more than directed unless directed by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

STOP USE AND ASK DOCTOR IF

- condition worsens, symptoms persist for more than 7 days or clear up and occur

again within a few days

- do not begin the use of any other hydrocortisone product unless directed by a doctor
- rectal bleeding occurs

KEEP OUT OF REACH OF CHILDREN

If swallowed, get medical help or contact a Poison Control Center {1-800-222-1222} 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 of age: consult a doctor
- for external anal and genital itching
- adults: when practical, clean the affected area with mild soap and warm water; rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: consult a doctor

OTHER INFORMATION

- store at 15°C to 30°C (59°F to 86°F). Protect from freezing.
- before using any medication, read all label directions. Keep carton, it contains important information.

INACTIVE INGREDIENT

aloe vera concentrate, cetyl alcohol, citric acid*, glyceryl stearate, isopropyl myristate, methyl paraben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate, solution*, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax

*Contains one or more of these ingredients to adjust pH

QUESTIONS?

Call 1-833-285-4151

PRINCIPAL DISPLAY PANEL

Hydrocortisone Cream USP, 1% with Aloe

Anti-itch Cream

Net wt. 1 oz (28g)

HYDROCORTISONE WITH ALOE

hydrocortisone cream

Maximum Strength Hydrocortisone Cream USP, 1% with Aloe

Anti-itch Cream

NDC 21922-097-04

Net wt. 0.5 oz (14 g)

Drug Facts

Active ingredient
Hydrocortisone USP, 1%

Purpose
Anti-Itch

Uses ■ temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to
■ eczema ■ psoriasis ■ insect bites ■ poison ivy, oak, sumac
■ detergents ■ jewelry ■ cosmetics ■ soaps ■ seborrheic dermatitis
■ temporarily relieves external anal and genital 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: ■ 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 the eyes
■ do not use more than directed unless directed 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
■ do not begin the use of any other hydrocortisone product unless directed by a doctor
■ rectal bleeding occurs
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Drug Facts (continued)

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: consult a doctor
■ for external anal and genital itching
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■ gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
■ apply to affected area not more than 3 to 4 times daily
■ children under 12 years of age: consult a doctor

Other information
■ store at 15°C to 30°C (59°F to 86°F). Protect from freezing.
■ before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients aloe vera concentrate, cetyl alcohol, citric acid*, glyceryl stearate, isopropyl myristate, methylparaben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate solution*, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax
*Contains one or more of these ingredients to adjust pH

Questions or comments?
Call 1-833-285-4151

This product is not manufactured or distributed by Bausch Health US, LLC, distributor of Maximum Strength Cortaid®.

Manufactured by:
Encube Ethicals Pvt. Ltd.
Plot No. C-1, Madkaim Industrial Estate, Madkaim, Post: Mardol, Ponda, Goa - 403 404, India.

Distributed by:
Encube Ethicals, Inc.
200 Meredith Drive, Suite 202, Durham, NC 27713, USA

Mfg. Lic. No.: 361

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EMBOSSING AREA

ECX3B/00

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-097	
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)		HYDROCORTISONE	1 g in 100 g	
Inactive Ingredients				
Ingredient Name			Strength	
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)				
POLYSORBATE 60 (UNII: CAL22UVI4M)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
WATER (UNII: 059QF0KO0R)				
SODIUM CITRATE (UNII: 1Q73Q2JULR)				
SORBIC ACID (UNII: X045WJ989B)				
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)				
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)				
WHITE WAX (UNII: 7G1J5DA97F)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21922-097-04	1 in 1 CARTON	02/26/2025	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21922-097-05	1 in 1 CARTON	02/26/2025	
2		28 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		M017	02/26/2025	

Labeler - Encube Ethicals, Inc. (116982244)

Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	ANALYSIS(21922-097) , LABEL(21922-097) , MANUFACTURE(21922-097) , PACK(21922-097)

Revised: 2/2025

Encube Ethicals, Inc.