

HYDROCORTISONE - hydrocortisone 1% ointment
Encube Ethicals, Inc.

Hydrocortisone Ointment 1%

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 INGREDIENTS

mineral oil, white petrolatum

QUESTIONS OR COMMENTS?

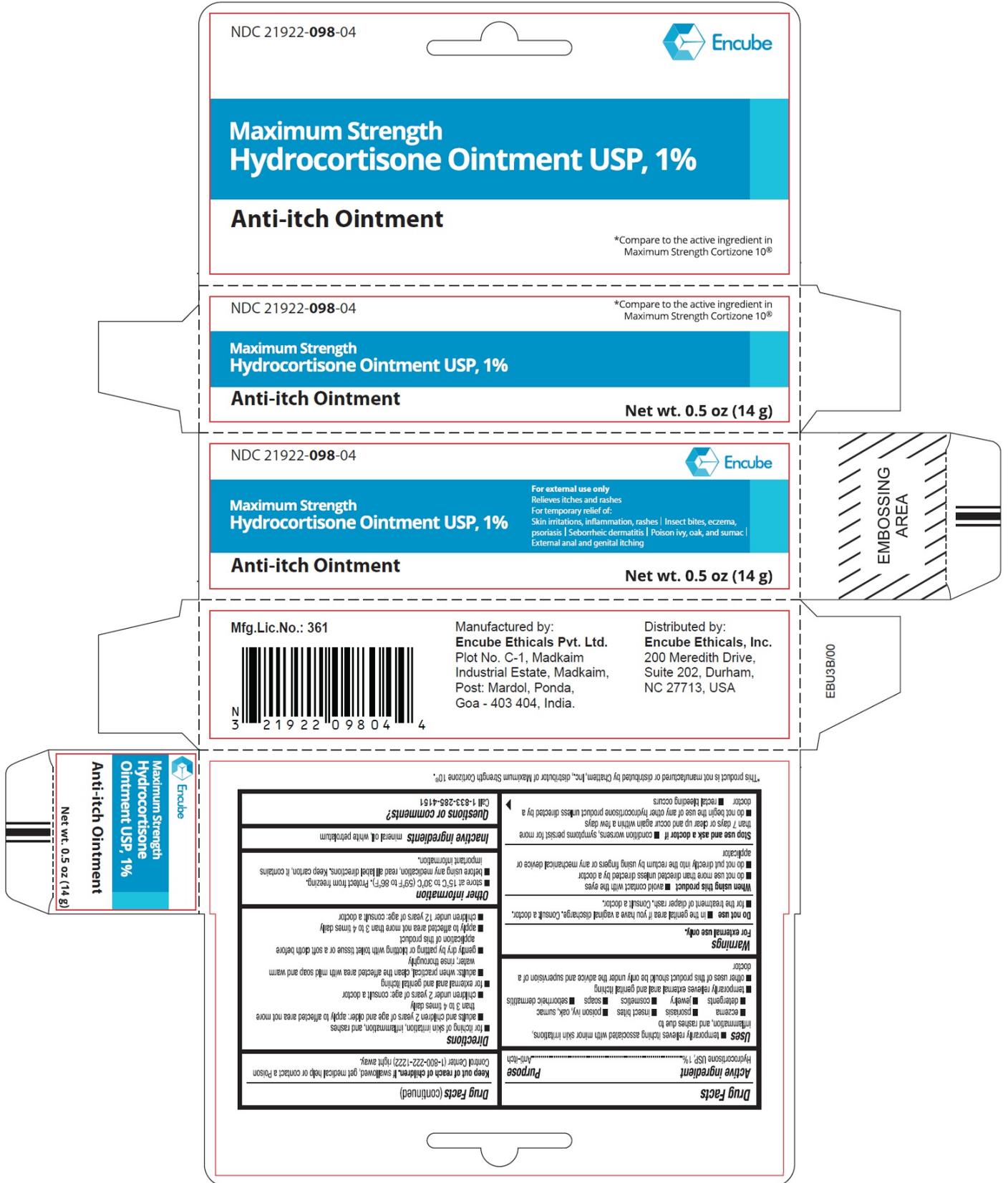
Call 1-833-285-4151

PRINCIPAL DISPLAY PANEL

Hydrocortisone Ointment USP, 1%

Anti-itch ointment

Net wt. 0.5 oz (14g)



Hydrocortisone Ointment USP, 1%
Anti-itch ointment

Net wt. 1 oz (28g)

NDC 21922-098-05 

Maximum Strength Hydrocortisone Ointment USP, 1%

Anti-itch Ointment

*Compare to the active ingredient in Maximum Strength Cortizone 10®

NDC 21922-098-05 *Compare to the active ingredient in Maximum Strength Cortizone 10®

Maximum Strength Hydrocortisone Ointment USP, 1%

Anti-itch Ointment

Net wt. 1 oz (28g)

NDC 21922-098-05 

Maximum Strength Hydrocortisone Ointment USP, 1%

Anti-itch Ointment

Net wt. 1 oz (28g)

For external use only
 Relieves itches and rashes
 For temporary relief of:
 Skin irritations, inflammation, rashes | Insect bites, eczema, psoriasis | Seborrheic dermatitis | Poison Ivy, oak, and sumac | External anal and genital itching

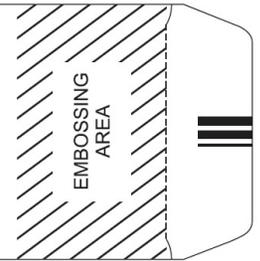
Mfg. Lic.No.: 361 Manufactured by:
Encube Ethicals Pvt. Ltd.
Plot No. C-1, Madkaim
Industrial Estate, Madkaim,
Post: Mardol, Ponda,
Goa - 403 404, India. Distributed by:
Encube Ethicals, Inc.
200 Meredith Drive,
Suite 202, Durham,
NC 27713, USA



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This product is not manufactured or distributed by Chatham, Inc., distributor of Maximum Strength Cortizone 10®.

<p>Drug Facts</p> <p>Active ingredient Hydrocortisone USP, 1%, Anti-itch</p> <p>Purpose Anti-itch</p> <p>Directions Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p>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.</p> <p>Warnings 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</p> <p>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</p> <p>Warnings other uses of this product should be only under the advice and supervision of a doctor temporarily relieves external and genital itching ■ eczema ■ psoriasis ■ insect bites ■ poison ivy, oak, sumac ■ detergents ■ jewelry ■ cosmetics ■ soaps ■ seborrheic dermatitis</p> <p>Warnings 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</p> <p>Questions or comments? Call 1-833-285-4151</p>	<p>Drug Facts (continued)</p> <p>Directions 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 washes when practical 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</p> <p>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.</p> <p>Warnings 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</p> <p>Questions or comments? Call 1-833-285-4151</p>
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Encube

Maximum Strength Hydrocortisone Ointment USP, 1%

Anti-itch Ointment

Net wt. 1 oz (28g)

HYDROCORTISONE

hydrocortisone 1% ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-098
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
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21922-098-04	1 in 1 CARTON	03/06/2025	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21922-098-05	1 in 1 CARTON	03/06/2025	
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	03/06/2025	

Labeler - Encube Ethicals, Inc. (116982244)

Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	analysis(21922-098) , label(21922-098) , manufacture(21922-098) , pack(21922-098)

Revised: 9/2025

Encube Ethicals, Inc.