

**HYDROCORTISONE- hydrocortisone cream**  
**Encube Ethicals, Inc.**

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**HYDROCORTISONE CREAM USP, 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 isopropyl 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**

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

## **PRINCIPAL DISPLAY PANEL**

# Hydrocortisone Cream USP, 1%

## Anti-itch Cream

Net wt. 1 oz (28g)

<b>Drug Facts</b> <b>Active ingredient</b> Hydrocortisone, USP 1% <b>Purpose</b> Anti-itch	<b>Drug Facts (continued)</b> <b>Directions</b> ■ 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
<b>Uses</b> ■ 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	<b>Other information</b> ■ 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.
<b>Warnings</b> <b>For external use only.</b> <b>Do not use</b> ■ in the genital area if you have a vaginal discharge. Consult a doctor. ■ for the treatment of diaper rash. Consult a doctor. <b>When using this product</b> ■ 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 <b>Stop use and ask a doctor if</b> ■ 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	<b>Inactive ingredients</b> cetyl alcohol, citric acid*, glyceryl stearate, isopropyl myristate, methylparaben, polyoxy 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sodium citrate solution*, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax <b>Questions or comments?</b> Call 1-833-285-4151
<b>Keep out of reach of children.</b> If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.	<small>*This product is not manufactured or distributed by Bausch Health US, LLC, distributor of Maximum Strength Cortaid®.</small>

Encube  
Maximum Strength  
Hydrocortisone Cream  
USP, 1%  
Anti-itch Cream  
Net wt. 1 oz (28g)

ECW3A/00

Mfg. Lic. No.: 361

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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

EMBOSSING  
AREA

Maximum Strength  
Hydrocortisone Cream USP, 1%  
Anti-itch Cream

Net wt. 1 oz (28g)

NDC 21922-096-05

Encube

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.

Maximum Strength  
Hydrocortisone Cream USP, 1%  
Anti-itch Cream

Net wt. 1 oz (28g)

NDC 21922-096-05

Compare to the active ingredient in  
Maximum Strength Cortaid®

Maximum Strength  
Hydrocortisone Cream USP, 1%  
Anti-itch Cream

Net wt. 1 oz (28g)

NDC 21922-096-05

Encube

Compare to the active ingredient in  
Maximum Strength Cortaid®

Hydrocortisone Cream USP, 1%

Anti-itch Cream

Net wt. 0.5 oz (14g)

<b>Drug Facts</b>		<b>Drug Facts (continued)</b>
<b>Active ingredient</b> Hydrocortisone, USP 1%	<b>Purpose</b> Anti-itch	<b>Directions</b> ■ 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 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
<b>Uses</b> ■ temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to: ■ eczema ■ psoriasis ■ insect bites ■ poison ivy, oak, sumac ■ dermatitis ■ jewelry ■ cosmetics ■ soaps ■ allergic dermatitis ■ temporarily relieves external and genital itching ■ other uses of this product should be only under the advice and supervision of a doctor.		<b>Other information</b> ■ store at 15°C to 30°C (59°F to 86°F). Protect from freezing. ■ before using any medication, read all labeled directions. Keep carton, it contains important information.
<b>Warnings</b> 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.		<b>Inactive ingredients</b> cetyl alcohol, citric acid*, glycerol stearate, lauryl myristate, methylparaben, polybutyl 4D stearate, polyoxalate 65, 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
<b>Questions or comments?</b> Call 1-833-285-4151		<small>*This product is not manufactured or distributed by Bausch Health US, LLC, distributor of Maximum Strength Cortaid®.</small>

Encube  
Maximum Strength Hydrocortisone Cream USP, 1%  
Anti-itch Cream  
Net wt. 0.5 oz (14 g)

Mfg. Lic. No.: 361  
N 3 2 1 9 2 2 0 9 6 0 4  
Manufactured by:  
Encube Ethicals Pvt. Ltd.  
Plot No. C-1, Madkaim  
Industrial Estate, Madkaim,  
Goa - 403 404, India.  
Distributed by:  
Encube Ethicals, Inc.  
200 Meredith Drive,  
Suite 202, Durham,  
NC 27713, USA  
ECW3B/00

Maximum Strength Hydrocortisone Cream USP, 1%  
Anti-itch Cream  
NDC 21 922-096-04  
Net wt. 0.5 oz (14 g)  
For external use only.  
Relieves itching and rashes.  
Temporary relief.  
Eczema, psoriasis, dermatitis, allergic reactions, insect bites, poison ivy, oak, and sumac. External and genital itching.

Maximum Strength Hydrocortisone Cream USP, 1%  
Anti-itch Cream  
NDC 21 922-096-04  
Net wt. 0.5 oz (14 g)  
Compare to the active ingredient in Maximum Strength Cortaid®

Maximum Strength Hydrocortisone Cream USP, 1%  
Anti-itch Cream  
NDC 21 922-096-04  
Compare to the active ingredient in Maximum Strength Cortaid®

EMBOSSING AREA

# HYDROCORTISONE

hydrocortisone cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21922-096
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>POLYOXYL 40 STEARATE</b> (UNII: 13A4J4NH9I)	
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)	
<b>SORBIC ACID</b> (UNII: X045WJ989B)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>WHITE WAX</b> (UNII: 7G1J5DA97F)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:21922-096-04	1 in 1 CARTON	02/25/2025	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:21922-096-05	1 in 1 CARTON	02/25/2025	
2		28 g in 1 TUBE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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OTC Monograph Drug	M017	02/25/2025	
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**Labeler -** Encube Ethicals, Inc. (116982244)

**Establishment**

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	ANALYSIS(21922-096) , LABEL(21922-096) , MANUFACTURE(21922-096) , PACK(21922-096)

Revised: 11/2025

Encube Ethicals, Inc.