

HYDROCORTISONE - hydrocortisone cream
Encube Ethicals, Inc.

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?

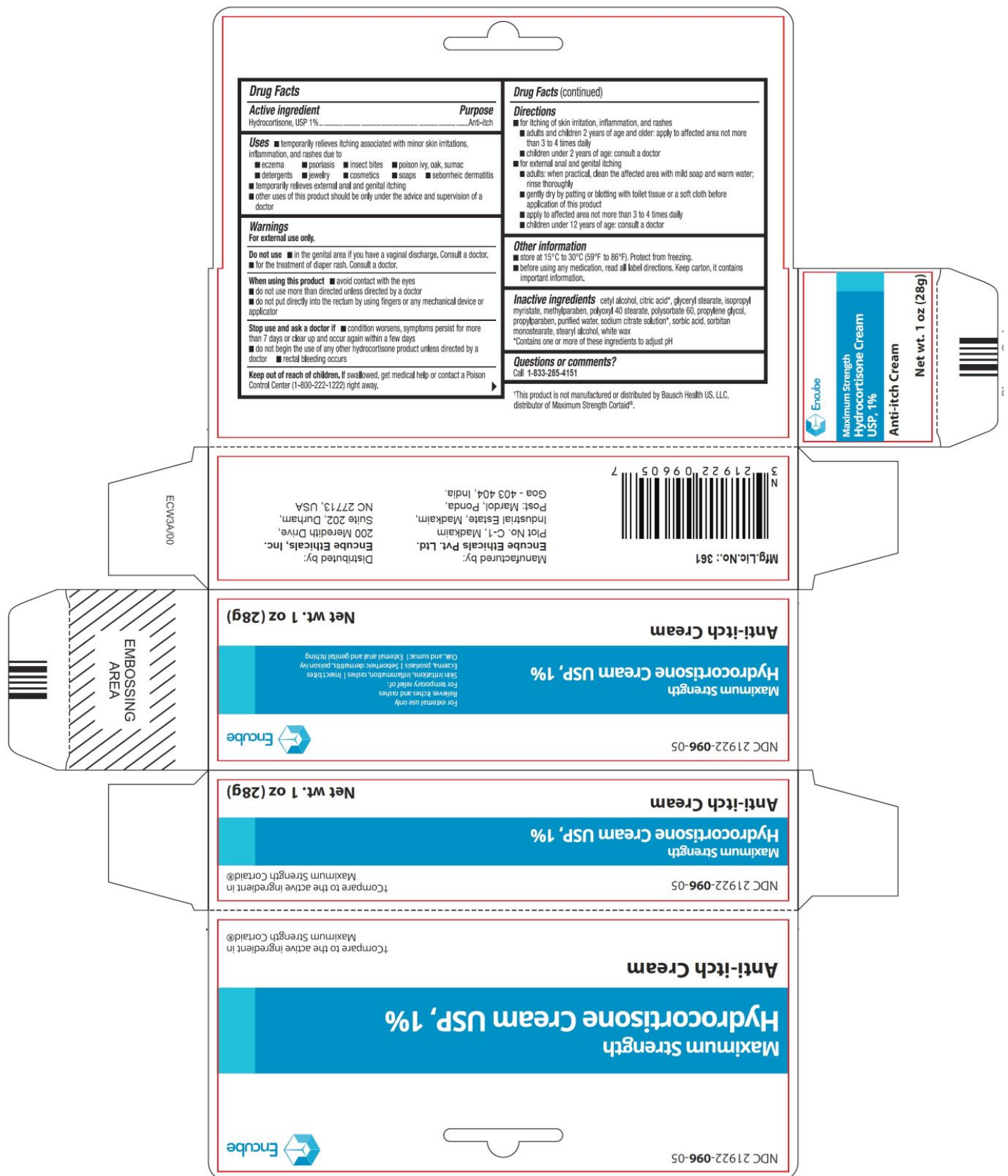
Call 1-833-285-4151

PRINCIPAL DISPLAY PANEL

Hydrocortisone Cream USP, 1%

Anti-itch Cream

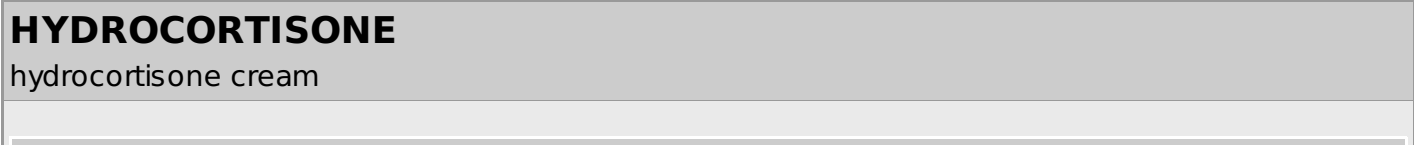
Net wt. 1 oz (28g)



Hydrocortisone Cream USP, 1%
 Anti-itch Cream

HYDROCORTISONE

hydrocortisone cream



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-096	
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	
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:21922-096-04	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				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug		M017	02/25/2025	

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: 2/2025

Encube Ethicals, Inc.