# 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 ether 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 genial 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

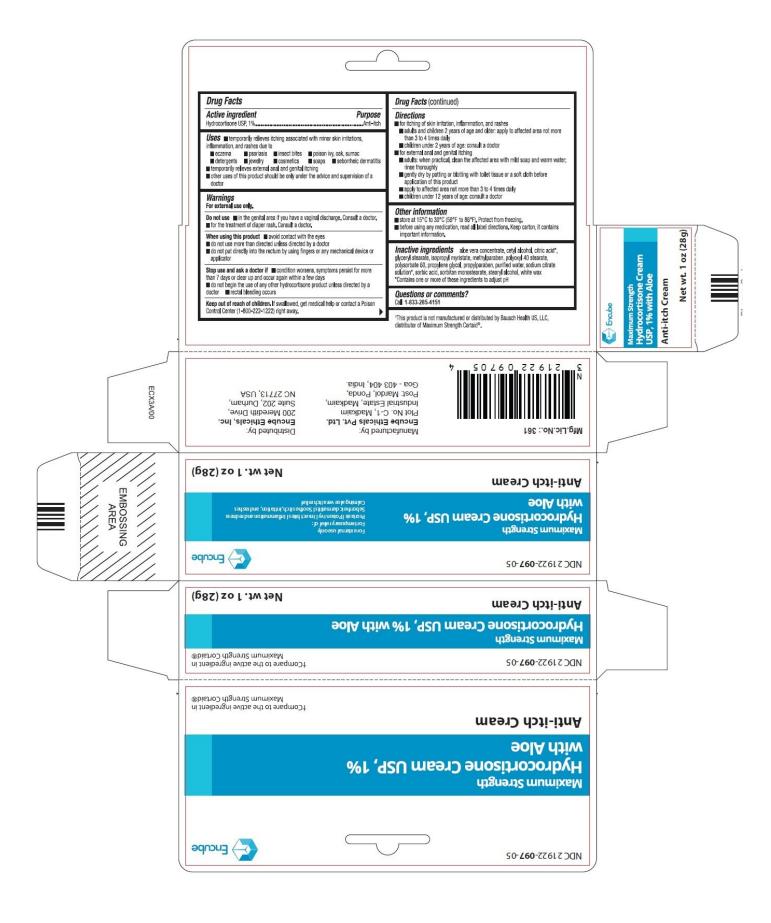
\*Contains one or more of these ingredients to adjust pH

#### **QUESTIONS?**

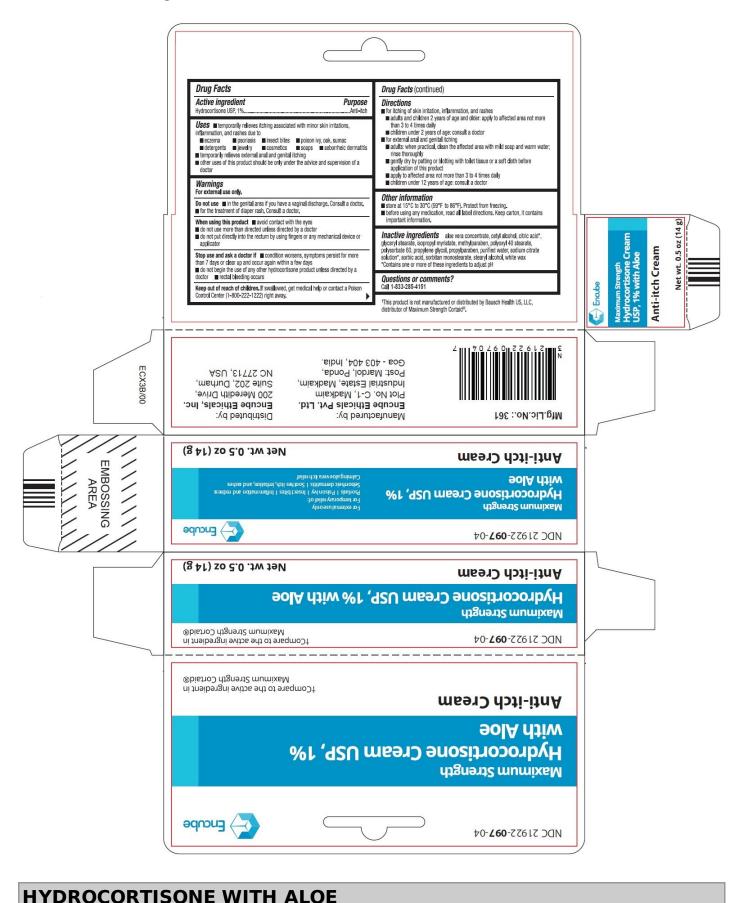
Call 1-833-285-4151

### PRINCIPAL DISPLAY PANEL

Hydrocortisone Cream USP, 1% with Aloe Anti-itch Cream Net wt. 1 oz (28g)



hydrocortisone cream



Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21922-097
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety			
Ingredient Name	<b>Basis of Strength</b>	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: 2300U9XXE4)			
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)			
METHYLPARABEN (UNII: A218C7H19T)			
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)			
POLYSORBATE 60 (UNII: CAL22UVI4M)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC10H)			
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.