

**HYDROCORTISONE - hydrocortisone 1% ointment**  
**Encube Ethicals Private Limited**

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**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?**

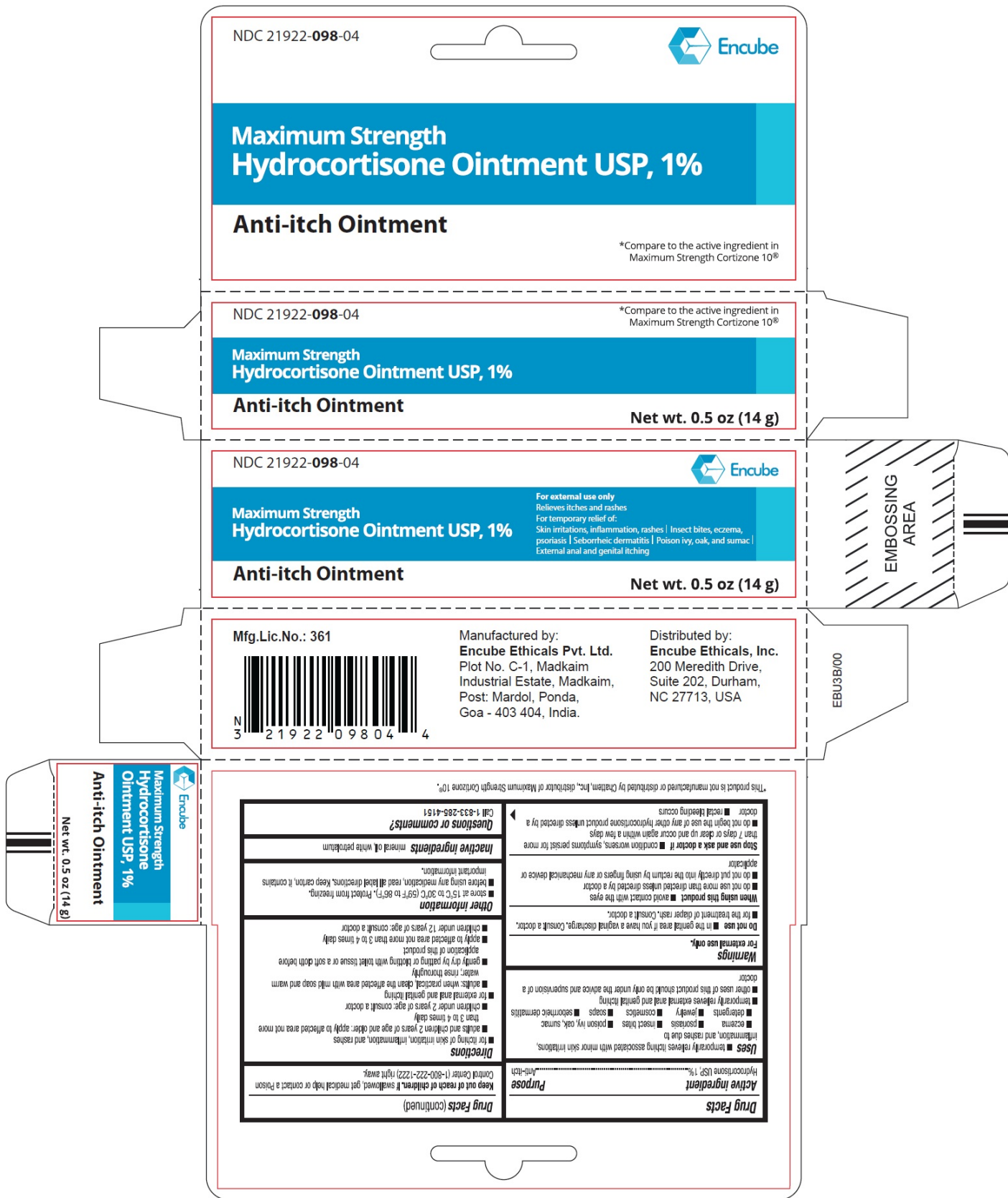
Call 1-833-285-4151

## **PRINCIPAL DISPLAY PANEL**

Hydrocortisone Ointment USP, 1%

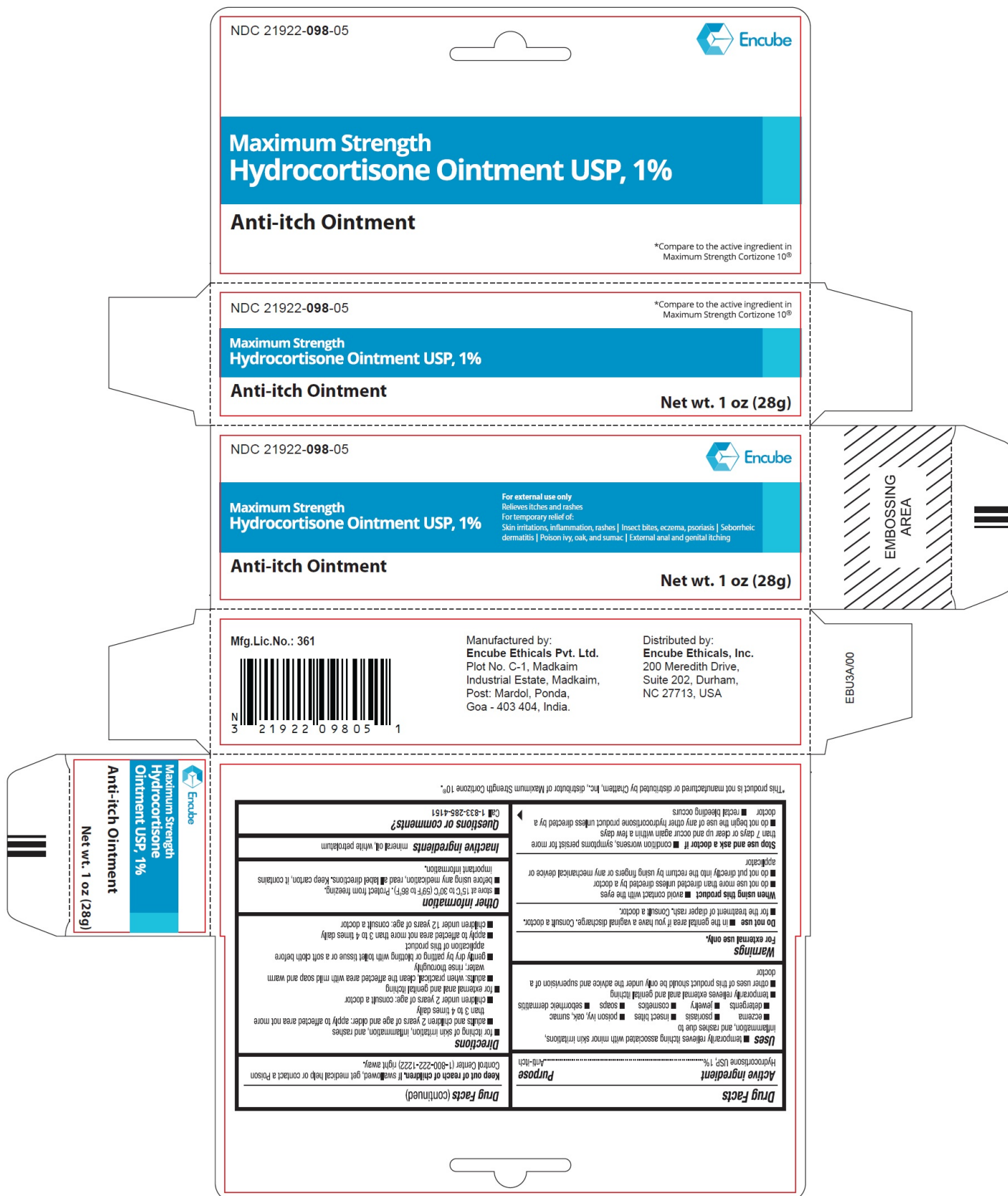
Anti-itch ointment

Net wt. 0.5 oz (14g)



Hydrocortisone Ointment USP, 1%  
Anti-itch ointment

Net wt. 1 oz (28g)



# HYDROCORTISONE

hydrocortisone 1% ointment

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:21922-098
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (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 Private Limited (915834105)

## Establishment

Name	Address	ID/FEI	Business Operations
Encube Ethicals Private Limited		725076298	ANALYSIS(21922-098) , LABEL(21922-098) , MANUFACTURE(21922-098) , PACK(21922-098)