

## **BUDPAK ANTI-ITCH- hydrocortisone cream**

**Budpak Inc.**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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### ***Active Ingredient***

Hydrocortisone 1%

### ***Purpose***

Anti-itch

### ***Uses***

for the temporary relief of itching associated with minor skin irritations and rashes due to:

- eczema
- seborrheic dermatitis
- psoriasis
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- external genital, feminine and anal itching

Other uses or the use of the product for more than 7 days should be undertaken 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. Ask a doctor.

#### **When using this product**

- avoid contact with eyes
- do not use more than directed unless told to do so 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

#### **Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center 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: Ask a doctor

**for external anal and genital itching, adults:**

- when practical, clean the affected area with mild soap and water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: Ask a doctor

***Other information***

- Store at room temperature
- Lot No. & Exp. Date: see crimp of tube

***Inactive Ingredients***

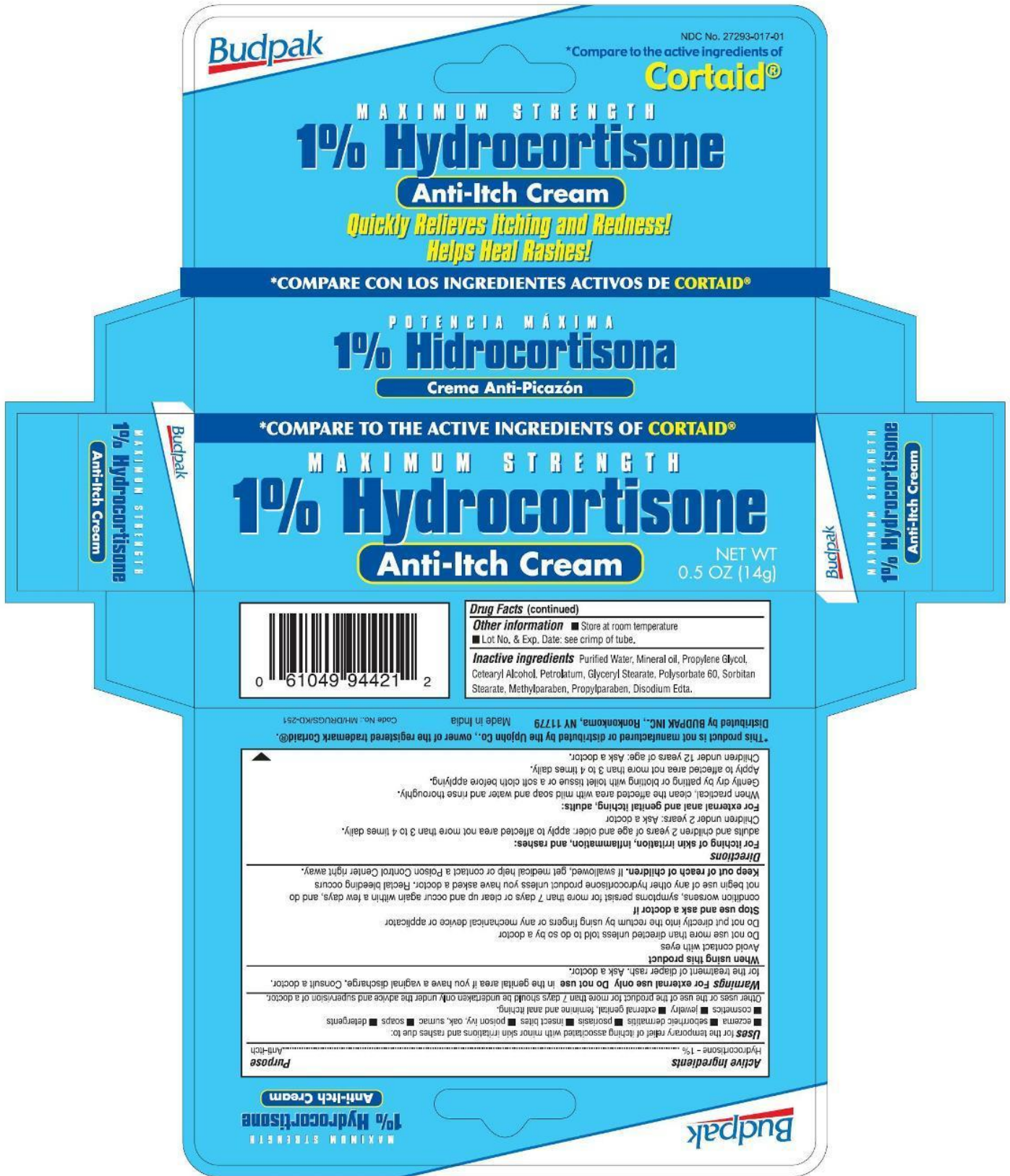
Purified Water, Mineral Oil, Propylene Glycol, Cetearyl Alcohol, Petrolatum, Glyceryl Stearate, Polysorbate 60, Sorbitan Stearate, Methylparaben, Propylparaben, Disodium Edta

**PRINCIPAL DISPLAY PANEL**

BUDPAK ANTI-ITCH CREAM

Hydrocortisone 1%

NET WT 0.5 OZ. (14 g)



## BUDPAK ANTI-ITCH

hydrocortisone cream

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:27293-017

Route of Administration TOPICAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
MINERAL OIL (UNII: T5L8T28FGP)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
PETROLATUM (UNII: 4T6H12BN9U)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE SODIUM (UNII: MP1J8420LU)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27293-017-01	1 in 1 BOX		
1	NDC:27293-017-14	14 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/17/2012	

**Labeler** - Budpak Inc. (183224849)

**Registrant** - Anicare Pharmaceuticals Pvt. Ltd (916837425)

### Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Pvt. Ltd		916837425	manufacture(27293-017)