#### 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     |                |                    |               |  |  |  |
|---|----------------------|----------------|--------------------|---------------|--|--|--|
| I | hydrocortisone cream |                |                    |               |  |  |  |
|   |                      |                |                    |               |  |  |  |
|   | Product Information  |                |                    |               |  |  |  |
|   | Product Type         | HUMAN OTC DRUG | Item Code (Source) | NDC:27293-017 |  |  |  |
|   |                      |                |                    |               |  |  |  |

| Route | of Administration |  |
|-------|-------------------|--|
|-------|-------------------|--|

| Active Ingredient/Active Moiety         Basis of Strength         Strength           HyproCORTISONE (UNIE WIAX0X7BPJ) (HYDROCORTISONE - UNIEWIAX0X7BPJ)         HYDROCORTISONE (UNIE WIAX0X7BPJ) (HYDROCORTISONE - UNIEWIAX0X7BPJ)           Ingredient Name         Strength           MINERAL OIL (UNIE 059QF0K00R)           MINERAL OIL (UNIE 51E1728FGP)         Strength  |  |                                 |                  |                |               |                 |  |  |
|---|--|---------------------------------|------------------|----------------|---------------|-----------------|--|--|
| HYDRO CORTISONE (UNIE: WI4X0 X7BPJ) (HYDROCORTISONE - UNIE:WI4X0 X7BPJ)       HYDROCORTISONE (D. 0.01 g in 1 g         Ingredients         Ingredient Name       Strength         WATER (UNIE: 059QF0K00R)       Ingredient Name       Strength         WATER (UNIE: 059QF0K00R)       Ingredient Name       Strength         WATER (UNIE: 059QF0K00R)       Imgredient Name       Strength         PROPYLENE GLYCOL (UNIE: 050Q9 167V3)       Imgredient Name       Strength         PETROLATUM (UNIE: 40D9Q 160PQ 1280019 XE4)       Imgredient Name       Imgredient Name         OPLYSORBATE 6 00 (UNIE: CAL22UVI4M)       Imgredient Namo STEARATE (UNIE: N2400H58X)         METHYLPARABEN (UNIE: 228C7H9T)       Imgredient Name       Imgredient Name         POPYLPARABEN (UNIE: 228C7H9T)       Imgredient Name       Imgredient Name         METHYLPARABEN (UNIE: 228C7H9T)       Imgredient Name       Imgredient Name         Imgredient Solution (UNIE: MP18420LU)       Imgredient Name         Imgredient Name       Imgredient Name         Imgredient Name <th col<="" th=""><th colspan="7">Active Ingredient/Active Moiety</th></th>   | <th colspan="7">Active Ingredient/Active Moiety</th> | Active Ingredient/Active Moiety |                  |                |               |                 |  |  |
| Ingredient Name       Strength         WATER (UNE: 059QF0K00R)       Ingredient Name       Strength         MINERAL 0IL (UNE: 059QF0K00R)       Imgredient Name       Strength         MINERAL 0IL (UNE: 059QF0K00R)       Imgredient Name       Strength         PROPYLENE GL YCOL (UNE: 512878FGP)       Imgredient Name       Strength         PROPYLENE GL YCOL (UNE: 2DMT128MIS)       Imgredient 2000 9 X864)       Strength         PETROLATUM (UNE: 4THE 2DMT128MIS)       Imgredient 2000 9 X864)       Strength       Imgredient 2000 9 X864)       Imgredient 2000 9 X864)       Strength       Imgredient 2000 9 X864)       Imgredient 200   |  | Ingredient Name                 |                  | Ba             | sis of Streng | th Strength     |  |  |
| Ingredient NameStrengthWATER (UNIE 059QF0KOOR) <t< td=""><td>HYDROCORTISONE (UNI</td><td>I: WI4X0X7BPJ) (HYDROCORTISONE</td><td>E - UNII:WI4X0X7</td><td>BPJ) HYD</td><td>ROCORTISON</td><td>E 0.01g in 1g</td></t<>  | HYDROCORTISONE (UNI                                  | I: WI4X0X7BPJ) (HYDROCORTISONE  | E - UNII:WI4X0X7 | BPJ) HYD       | ROCORTISON    | E 0.01g in 1g   |  |  |
| Ingredient NameStrengthWATER (UNIE 059QF0KOOR) <t< th=""><th></th><th></th><th></th><th></th><th></th><th></th></t<>  |  |                                 |                  |                |               |                 |  |  |
| WATER (UNIE: 059QF0 KOOR)         MINERAL OIL (UNIE: T5L8728 FGP)         Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2">Image: Colspan="2"         PROPYLENE GLYCOL (UNIE: 2002 Q167V3)         CETOSTEARYL ALCOHOL (UNIE: 2007 Q20167V3)         Image: Colspan="2">Image: Colspan="2"         Image: Colspan="2">Image: Colspan="2"         Image: Colspan="2" <t< td=""><td>Inactive Ingredients</td><td></td><td></td><td></td><td></td><td></td></t<>  | Inactive Ingredients                                 |                                 |                  |                |               |                 |  |  |
| MINERAL OIL (UNII: 51324FGP)       identifies         PYLENE GLYCOL (UNII: 50C9Q167V3)       identifies         CET>STEARYL ALCOHOL (UNII: 2DMT128MIS)       identifies         PETROLATUM (UNII: 416)       identifies         PETROLATUM (UNII: 41762000000000000000000000000000000000000   |  | Ingredient Name                 | e                |                |               | Strength        |  |  |
| PRO PYLENE GLYCOL (UNI: 6D.9.9(167V3))       Image: Signature of Sign        | WATER (UNII: 059QF0KO                                | )R)                             |                  |                |               |                 |  |  |
| CETO STEARYL ALCOHOL (UNI: 2DMT128M1S)       Image: Comparing the state of the sta        | MINERAL OIL (UNII: T5L8                              | T28FGP)                         |                  |                |               |                 |  |  |
| PETRO LATUM (UNII: 4T6 Hi2BN9U)       indicinal display in the integration of the integ        | PROPYLENE GLYCOL (U                                  | NII: 6DC9Q167V3)                |                  |                |               |                 |  |  |
| GIVERVL MONOSTEARATE (UNI: 2300U9XXE4)       Image: Colspan="4">Gite Cols                    | CETOSTEARYL ALCOHO                                   | L (UNII: 2DMT128M1S)            |                  |                |               |                 |  |  |
| POLYSORBATE 60 (UNI: CAL22UVI4M)       indicition       indicitien  | PETROLATUM (UNII: 4T6)                               | H12BN9U)                        |                  |                |               |                 |  |  |
| S R BIT AN MONOS TEARATE (UNII: NVZ410 H58 X)       Image: Signed State St        | GLYCERYL MONOSTEAR                                   | RATE (UNII: 230OU9XXE4)         |                  |                |               |                 |  |  |
| Image: Name of the state | POLYSORBATE 60 (UNII:                                | CAL22UVI4M)                     |                  |                |               |                 |  |  |
| PYLPARABEN (UNI: ZIZSC1OH)       Image: Size Cione Cion         | SORBITAN MONOSTEAR                                   | ATE (UNII: NVZ4I0H58X)          |                  |                |               |                 |  |  |
| # Item Code Package Description Marketing Start Date Marketing End Date   1 NDC:27293-017-01 1 in 1 BOX Image: Start Date Image: Start Date   2 NDC:27293-017-14 14 g in 1 TUBE Image: Start Date Image: Start Date   | METHYLPARABEN (UNII:                                 | A218C7HI9T)                     |                  |                |               |                 |  |  |
| Package Description       Marketing Start Date         #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:27293-017-01       1 in 1 BOX       Image: Colspan="5">Image: Colspan="5" Image: Colspan="5">Image: Colspan="5" Image: Colspan="5">Image: Colspan="5" Image:  | PROPYLPARABEN (UNII: 2                               | Z8IX2SC1OH)                     |                  |                |               |                 |  |  |
| #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:27293-017-01       1 in 1 BOX       Image: Comparison of the temperature       Image: Comparison of temperature         1       NDC:27293-017-14       14 g in 1 TUBE       Image: Comparison of temperature       Image: Comparison of temperature         Variable       Image: Comparison of temperature       Image: Comparison of temperature       Image: Comparison of temperature         Marketing Category       Application Number or Monograph Citation       Marketing Start Date       Marketing End Date   | EDETATE SO DIUM (UNII: ]                             | MP1J8420LU)                     |                  |                |               |                 |  |  |
| #       Item Code       Package Description       Marketing Start Date       Marketing End Date         1       NDC:27293-017-01       1 in 1 BOX   |  |                                 |                  |                |               |                 |  |  |
| 1       NDC:27293-017-01       1 in 1 BOX       Image: Comparison of the compari                          | Packaging  |                                 |                  |                |               |                 |  |  |
| 1       NDC:27293-017-14       14 g in 1 TUBE         If g in 1 TUBE         Warketing Information         Marketing Category         Application Number or Monograph Citation       Marketing Start Date       Marketing End Date  | # Item Code  | Package Description             | Marketing        | Start Date     | Marketi       | ng End Date     |  |  |
| Marketing InformationMarketing CategoryApplication Number or Monograph CitationMarketing Start DateMarketing End Date   | 1 NDC:27293-017-01                                   | 1 in 1 BOX                      |                  |                |               |                 |  |  |
| Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date   | 1 NDC:27293-017-14                                   | 14 g in 1 TUBE                  |                  |                |               |                 |  |  |
| Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date   |  |                                 |                  |                |               |                 |  |  |
| Marketing Category Application Number or Monograph Citation Marketing Start Date Marketing End Date   |  |                                 |                  |                |               |                 |  |  |
|   | Marketing Information                                |                                 |                  |                |               |                 |  |  |
| OTC monograph not final part348 12/17/2012  | Marketing Category                                   | Application Number or Monog     | raph Citation    | Marketing Star | rt Date Mar   | keting 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    | <b>Business Operations</b> |
|----------------------------------|---------|-----------|----------------------------|
| Anicare Pharmaceuticals Pvt. Ltd |         | 916837425 | manufacture(27293-017)     |

Revised: 1/2013

Budpak Inc.