

LIVE BETTER HYDROCORTISONE WITH ALOE- hydrocortisone cream
The Great Atlantic & Pacific Tea Company

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.

Live Better
Hydrocortisone with Aloe

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch cream

Uses

- temporary relief of itching associated with minor skin irritations and rashes due to
 - eczema
 - insect bites
 - poison ivy, poison oak, or poison sumac
 - soaps
 - detergents
 - cosmetics
 - jewelry
 - seborrheic dermatitis
 - psoriasis
 - external genital and anal 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 eyes
- by putting this product into the rectum by using fingers or any mechanical device or applicator

Ask a doctor before use if you have

- a vaginal discharge
- rectal bleeding
- diaper rash

When using this product consult a doctor before exceeding recommended dosage

Stop use and ask a doctor if

- condition gets worse
- condition persists for more than 7 days
- condition clears up and occurs again within a few days. Do not begin to use any other

hydrocortisone product unless you have consulted a doctor.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions

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: do not use. consult a doctor

For external anal itching

- Adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product

Children under 12 years of age: consult a doctor

Other information

- To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- store at room temperature
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

aloe barbadensis, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, citric acid, glycerin, glyceryl stearate, methylparaben, mineral oil, paraffin, propylparaben, purified water, stearyl alcohol

Questions?

Call **1-866-923-4914**

DISTRIBUTED BY ONPOINT, INC.

2 PARAGON DRIVE,
MONTVALE, NJ 07645

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

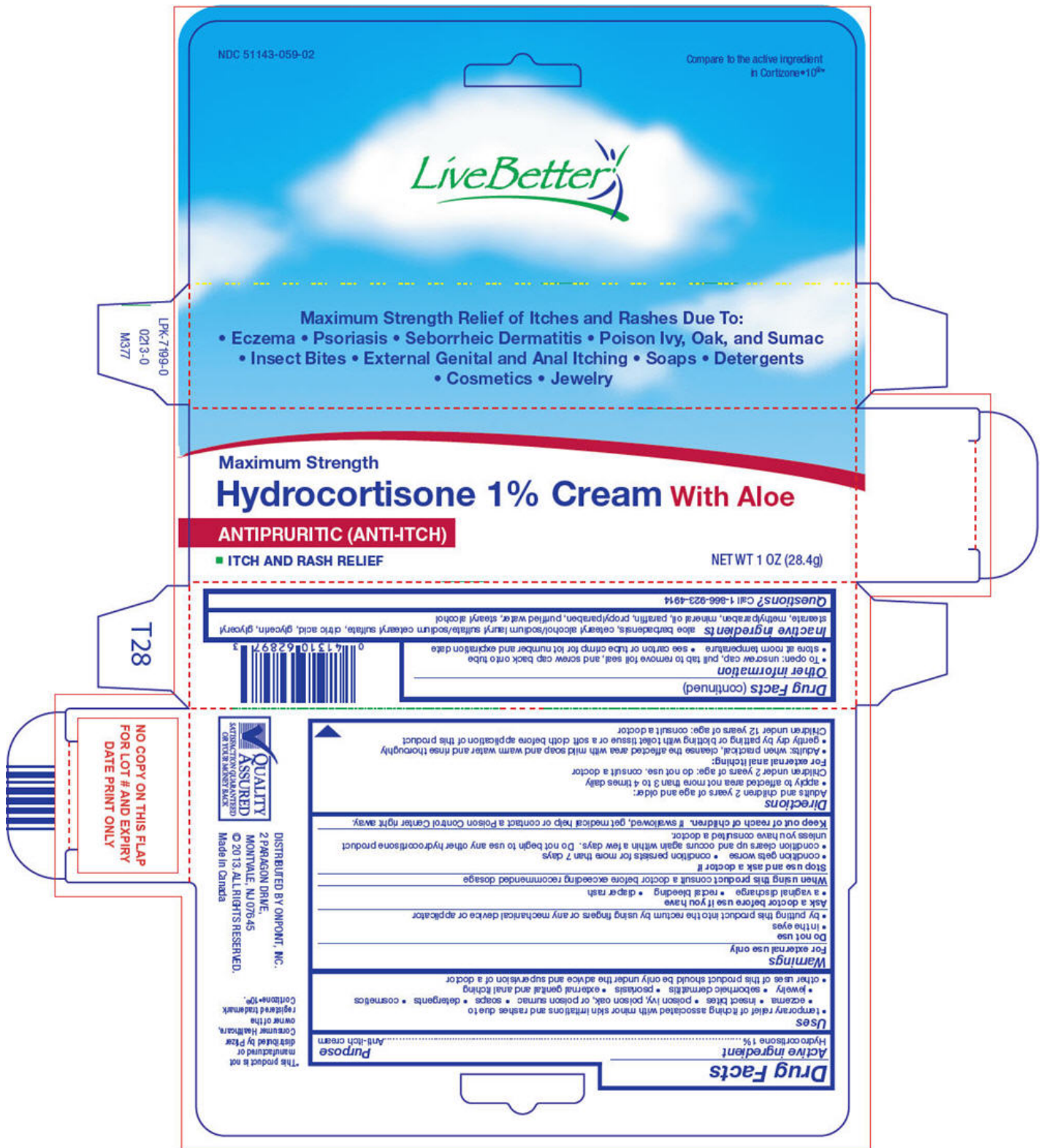
Maximum Strength

Hydrocortisone 1% Cream With Aloe

ANTIPRURITIC (ANTI-ITCH)

- **ITCH AND RASH RELIEF**

NET WT 1 OZ (28.4g)



LIVE BETTER HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:51143-059 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ) | Hydrocortisone | 1 g in 100 g |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| cetostearyl alcohol (UNII: 2DMT128M1S) | |
| sodium lauryl sulfate (UNII: 368GB5141J) | |
| sodium cetostearyl sulfate (UNII: 7ZBS06BH4B) | |
| citric acid monohydrate (UNII: 2968PHW8QP) | |
| glycerin (UNII: PDC6A3C0OX) | |
| glyceryl monostearate (UNII: 230OU9XXE4) | |
| methylparaben (UNII: A218C7H9T) | |
| mineral oil (UNII: T5L8T28FGP) | |
| paraffin (UNII: I9O0E3H2ZE) | |
| propylparaben (UNII: Z8IX2SC1OH) | |
| water (UNII: 059QF0K00R) | |
| stearyl alcohol (UNII: 2KR89I4H1Y) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:51143-059-02 | 1 in 1 CARTON | | |
| 1 | | 28.4 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC MONOGRAPH NOT FINAL | part348 | 08/23/1995 | |

Labeler - The Great Atlantic & Pacific Tea Company (001367366)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

| Name | Address | ID/FEI | Business Operations |
|---------------------------|---------|-----------|------------------------|
| Taro Pharmaceuticals Inc. | | 206263295 | MANUFACTURE(51143-059) |