HYDROCORTISONE- hydrocortisone cream
Proficient Rx LP

Hydrocortisone ½%

Drug Facts

Active ingredient

Hydrocortisone 0.5%

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

Questions?

Call 1-866-923-4914

Distributed by:
Taro Pharmaceuticals U.S.A., Inc.
Hawthorne, NY 10532

Relabeled by:
Proficient Rx LP
Thousand Oaks, CA 91320

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

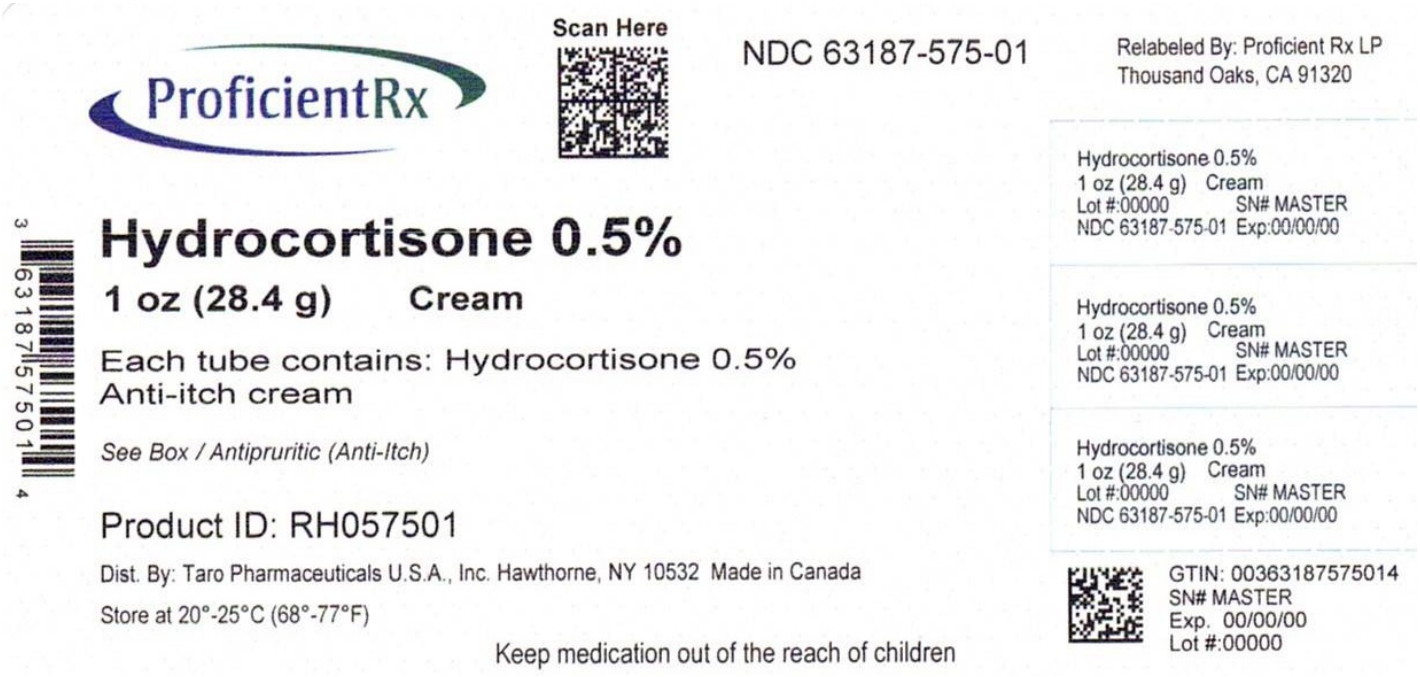
Itch and Rash Relief

Sensitive Skin

Hydrocortisone ½%
Cream
Antipruritic (Anti-Itch)

With Aloe

NET WT 1 oz (28.4 g)



HYDROCORTISONE
hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:63187-575(NDC:51672-2010)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrocortisone (UNII: W4X0X7BPJ) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone	0.5 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
cetostearyl alcohol (UNII: 2DMT128M1S)	
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
sodium lauryl sulfate (UNII: 368GB5141J)	
stearyl alcohol (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-575-01	1 in 1 CARTON	12/01/2018	
1		28.4 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	09/13/2001	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-575) , RELABEL(63187-575)

Revised: 2/2024 Proficient Rx LP