HYDROCORTISONE WITH ALOE- hydrocortisone cream Proficient Rx LP

Hydrocortisone 1% 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
 - o eczema
 - o insect bites
 - o poison ivy, poison oak, or poison sumac
 - o soaps
 - o detergents
 - o cosmetics
 - o jewelry
 - o seborrheic dermatitis
 - o psoriasis
 - o 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: **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

MAXIMUM STRENGTH

Hydrocortisone 1% Cream Antipruritic (Anti-Itch)

With Aloe

NET WT 1 oz (28.4 g)





NDC 63187-504-01

Relabeled By: Proficient Rx LP Thousand Oaks, CA 91320

Hydrocortisone 1% 1 oz (28.4g) Cream Lot #:00000 SN# MASTER NDC 63187-504-01 Exp:00/00/00

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Hydrocortisone

GTIN: 00363187504014 SN# MASTER Exp. 00/00/00 Lot #:00000

1 g in 100 g

1 oz (28.4g) Cream

Hydrocortisone 1%

Each tube contains: Hydrocortisone 1% Anti-itch cream

See Box. Antipruritic (Anti-Itch). Itch and Rash Relief with Aloe

Hydrocortisone (UNII: W4X0X7BPJ) (Hydrocortisone - UNII:W4X0X7BPJ)

Product ID: RH050401

Dist. By: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532 Made in Canada Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-504(NDC:	51672-2013)
Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
Ingredient Name		E	Basis of Strength	Strength

Ingredient Name	Strength
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: 1900E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-504- 01	1 in 1 CARTON	02/02/2015	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
Marketing Information				
	Marketing	Application Number or Monograph	Marketing Start	Marketing End

Category	Citation	Date	Date	l
OTC Monograph Drug	M017	08/23/1995		
				4

Labeler - Proficient Rx LP (079196022)

Establishment				
Name	Address	ID/FEI	Business Operations	
Proficient Rx LP		079196022	RELABEL(63187-504)	

Revised: 2/2024

Proficient Rx LP