

HYDROCORTISONE- hydrocortisone ointment

Proficient Rx LP

Hydrocortisone

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch ointment

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

Fractionated Coconut Oil, Methylparaben, Propylparaben, White Petrolatum

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%

Ointment

Antipruritic (Anti-Itch)

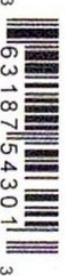
NET WT 1 oz (28.4 g)



Scan Here


NDC 63187-543-01

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320




Hydrocortisone 1%
1 oz (28.4 g) Ointment
Each tube contains: Hydrocortisone 1%
Anti-itch ointment
See Box / Antipruritic (Anti-Itch)
Product ID: RH054301
Dist. By: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532 Made in Canada
Store at room temperature
Keep medication out of the reach of children

Hydrocortisone 1%
1 oz (28.4 g) Ointment
Lot #:00000 SN# MASTER
NDC 63187-543-01 Exp:00/00/00

Hydrocortisone 1%
1 oz (28.4 g) Ointment
Lot #:00000 SN# MASTER
NDC 63187-543-01 Exp:00/00/00

Hydrocortisone 1%
1 oz (28.4 g) Ointment
Lot #:00000 SN# MASTER
NDC 63187-543-01 Exp:00/00/00

 GTIN: 00363187543013
SN# MASTER
Exp. 00/00/00
Lot #:00000

HYDROCORTISONE

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-543(NDC:51672-2018)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W4X0X7BPJ) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
------------------------	-----------------

Medium-chain triglycerides (UNII: C9H2L21V7U)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Petrolatum (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-543-01	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	10/03/1989	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-543) , RELABEL(63187-543)