HYDROCORTISONE MAXIMUM STRENGTH- hydrocortisone ointment
Proficient Rx LP

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.

Hydrocortisone Ointment Maximum Strength - Actavis

Drug Facts

Active ingredient

Hydrocortisone, USP 1%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:

- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- jewelry
- detergents
- cosmetics
- psoriasis
- seborrheic dermatitis
- for external genital, feminine 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

- for external feminine itching if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

avoid contact with the eyes
do not begin the use of any other hydrocortisone product unless directed by a doctor
for external anal itching:
do not use more than directed unless directed by a doctor
do not put this product into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- symptoms last for more than 7 days
- the condition gets worse
- symptoms clear up and occur again in a few days
- rectal bleeding occurs, consult doctor promptly

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, clean the affected area with mild soap and warm water, 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

- Store at room temperature 59°-86°F (15°-30°C).
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive ingredients

mineral oil, white petrolatum

Questions?

1-800-432-8534 between 9 am and 4 pm EST, Monday–Friday.

PRINCIPAL DISPLAY PANEL

Distributed by:

Actavis Pharma Inc.

Parsippany, NJ 07054

Relabeled by:

Proficient Rx LP

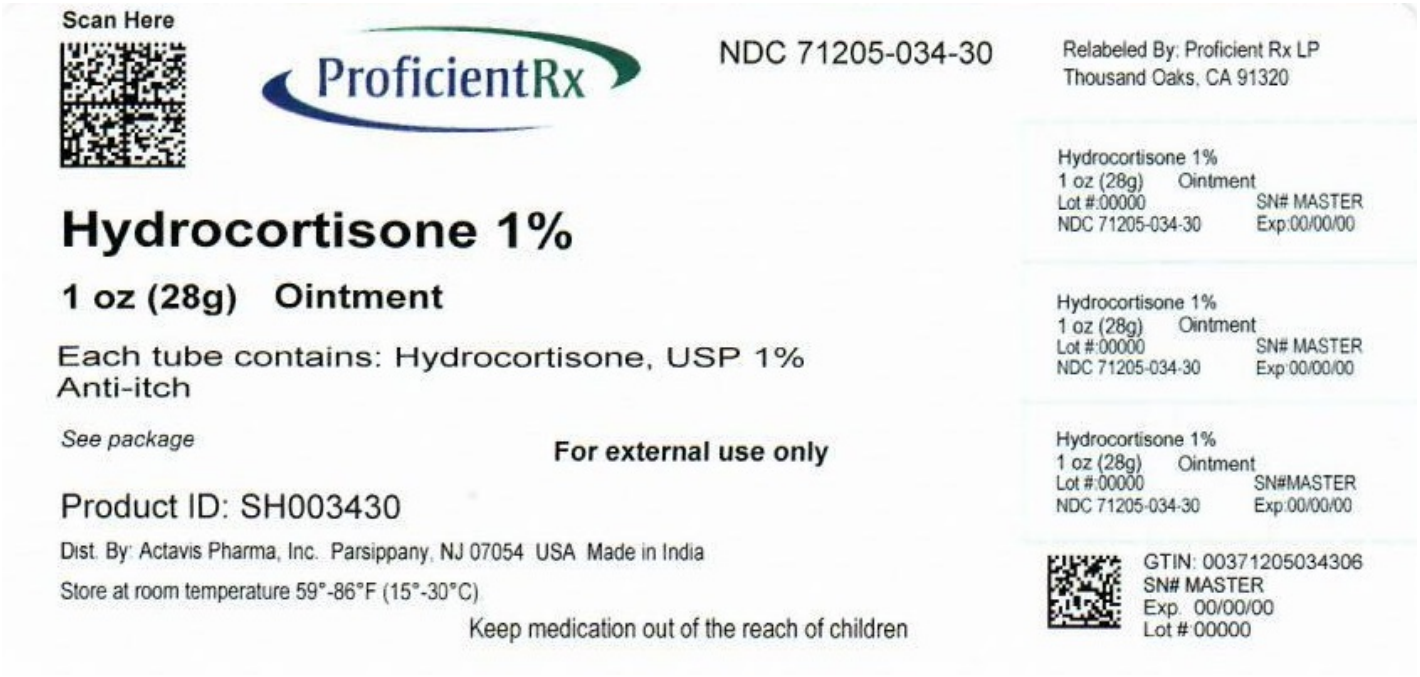
Thousand Oaks, CA 91320

Proficient Rx
NDC 71205-034-30
Compare to the active ingredient in Cortizone•10®*

Maximum Strength
Hydrocortisone Ointment, USP 1%
Anti-Itch Ointment

Relieves Itches and Rashes
Net wt. 1 oz (28g)

For the temporary relief of itches and rashes due to:
• Insect Bites • Eczema • Seborrheic dermatitis
• Poison Ivy, oak & sumac



HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone ointment

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71205-034(NDC:0472-0345)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71205-034-30	1 in 1 CARTON	05/01/2018	
1		28 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 not final	part348	07/21/1998	

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	RELABEL(71205-034)

Revised: 1/2021 Proficient Rx LP