

HYDROCORTISONE MAXIMUM STRENGTH WITH ALOE- hydrocortisone cream Proficient Rx LP

Hydrocortisone Cream, USP 1% with Aloe

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:

- o do not use more than directed unless directed by a doctor
- o 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). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

Inactive Ingredients

aloe vera concentrate, cetyl alcohol, glyceryl stearate, isopropyl myristate, methylparaben, polyoxyl 40 stearate, polysorbate 60, propylene glycol, propylparaben, purified water, sorbic acid, sorbitan monostearate, stearyl alcohol, white wax. May contain citric acid or sodium citrate solution to adjust pH.

Questions?

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

PRINCIPAL DISPLAY PANEL

Maximum Strength

Relabeled by:

Proficient Rx LP

Thousand Oaks, CA 91320

NDC 63187-567-01

Hydrocortisone ● 10

Hydrocortisone Cream, USP 1%

antipruritic (anti-itch) cream with Aloe

NET WT 1 OZ (28 g)

Compare to the Active ingredient in Cortizone • 10[®]*

Temporary Relief of Itching and Rashes Due to:

- Insect Bites
- Eczema
- Soaps
- Poison Ivy, Oak, Sumac
- Seborrheic Dermatitis
- Cosmetics
- Psoriasis
- Jewelry
- Detergents

03390311B1

VC110479

Rev 06/11



Scan Here



NDC 63187-567-01

Relabeled By: Proficient Rx LP
Thousand Oaks, CA 91320



Hydrocortisone 1%

1 oz (28 g) Cream

Each tube contains: Hydrocortisone, USP 1%
Anti-itch

See box. Antipruritic (anti-itch) cream

For external use only

Product ID: RH056701

Dist. By: MAJOR® PHARMACEUTICALS 17177 N Laurel Park Dr., Suite 233
Livonia, MI 48152 USA

Store at room temperature 59°-86°F (15°-30°C)

Keep medication out of the reach of children

Hydrocortisone 1%
1 oz (28 g) Cream
Lot #:00000 SN# MASTER
NDC 63187-567-01 Exp:00/00/00

Hydrocortisone 1%
1 oz (28 g) Cream
Lot #:00000 SN# MASTER
NDC 63187-567-01 Exp:00/00/00

Hydrocortisone 1%
1 oz (28 g) Cream
Lot #:00000 SN# MASTER
NDC 63187-567-01 Exp:00/00/00



GTIN: 00363187567019
SN# MASTER
Exp. 00/00/00
Lot #:00000

HYDROCORTISONE MAXIMUM STRENGTH WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63187-567(NDC:0904-7623)
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
WHITE WAX (UNII: 7G1J5DA97F)	
POLYOXYL 40 STEARATE (UNII: 13A4J4NH9I)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	

SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)

SORBIC ACID (UNII: X045WJ989B)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63187-567-01	1 in 1 CARTON	12/01/2018	
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 Drug	M017	04/21/2009	01/31/2025

Labeler - Proficient Rx LP (079196022)

Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-567) , RELABEL(63187-567)

Revised: 2/2024

Proficient Rx LP