

HYDROCORTISONE CREAM WITH ALOE- hydrocortisone cream

Rugby Laboratories

Rugby Hydrocortisone Cream 1% with Aloe

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Uses

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

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

Other uses of this product should be only under the advice and supervision of a doctor.

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) immediately.

Warnings

- for external use only
- avoid contact with eyes
- do not put this product into the rectum by using fingers or any mechanical device or applicator

For External Anal Itching Users:

- do not exceed the recommended daily dosage unless directed by a doctor
- in case of bleeding, consult a doctor promptly
- children under 12 years of age: consult a doctor

Before using any medication, read all label directions. Keep this carton as it contains important information

Do Not Use

- For the treatment of diaper rash, consult a doctor
- For the external genital itching if you have a vaginal discharge, consult a doctor

Stop using this product and ask a doctor if

- Conditions worsen
- symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor.

When using this product

- avoid contact with the eyes.
- do not begin the use of any other hydrocortisone product unless you have consulted a doctor
- for external genital, feminine and anal itching do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, stop use, consult a doctor.
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

Directions

Adults and children 2 years 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 and anal itching

- When practical, cleanse the affected area with mild soap and warm water and rinse thoroughly

by patting or blotting with toilet tissue or a soft cloth before application of this product.

- adults and children 12 years of age and older, apply to the affected area not more than 3 to 4 times daily
- children under 12 years of age with external anal itching: consult a doctor.

Inactive Ingredients

Aloe barbadensis leaf juice, Cetyl alcohol, Edetate Disodium, Methylparaben, Mineral Oil, Mono and di glycerides, petrolatum, Polysorbate 60, Propylene glycol, propylparaben, purified water, sorbitan monostearate.

Other Information

- store at controlled room temperature 20°-25°C (68°-77°F)

Other Information

Distributed By:

Rugby Laboratories®

Indianapolis, IN 46268

www.majorpharmaceuticals.com

1-800-616-2471

This product is not manufactured or distributed by Chattem, Inc. owner of the registered trademark Cortizone 10®

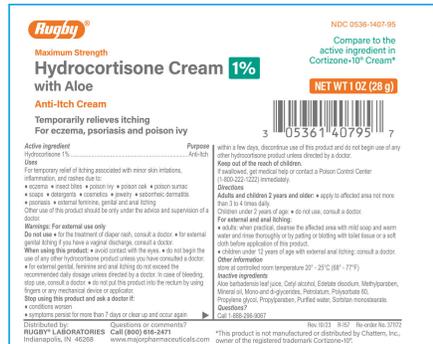
Package Label

OUTSIDE BOX





INNER TUBE



HYDROCORTISONE CREAM WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1407
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
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITAN MONOSTEARATE (UNII: NVZ410H58X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PETROLATUM (UNII: 4T6H12BN9U)	

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0K00R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
MINERAL OIL (UNII: T5L8T28FGP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1407-95	1 in 1 BOX	03/08/2024	
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	03/08/2024	

Labeler - Rugby Laboratories (079246066)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 12/2024

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