

RUGBY HYDROCORTISONE WITH ALOE- hydrocortisone cream

A-S Medication Solutions

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.

RUGBY® HYDROCORTISONE CREAM 1% WITH ALOE

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Antipruritic (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, detergents, cosmetics, jewelry
- and for external anal and genital itching.

Warnings

For external use only.

Avoid contact with eyes.

Do not use

- if you have a vaginal discharge. Consult a doctor.

When using this product

- do not exceed the recommended daily dosage unless directed by a doctor
- do not put into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days
- bleeding occurs

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

For itching associated with minor skin irritations, inflammation, and rashes:

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: Consult a doctor

For external anal and genital itching:

Adults and children 12 years of age and older:

- when practical, cleanse the affected area with mild soap or warm water and rinse thoroughly or by patting or blotting with an appropriate cleansing pad
- gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- apply to affected area not more than 3 to 4 times daily

Children under 12 years of age: Consult a doctor

Other information

Store at 15 to 30°C (59 to 86°F).

Tamper Evident: DO NOT USE IF SEAL ON TUBE IS BROKEN OR MISSING.

Inactive ingredients

aloe barbadensis leaf juice, carbomer, cetyl alcohol, DMDM hydantoin, glyceryl stearate, isopropyl alcohol, methylparaben, mineral oil, polysorbate-20, propylparaben, purified water, stearic acid, triethanolamine, trisodium EDTA

Questions or comments?

1-800-645-2158

Distributed by:

RUGBY® LABORATORIES

17177 N Laurel Park Drive, Suite 233

Livonia, MI 48152

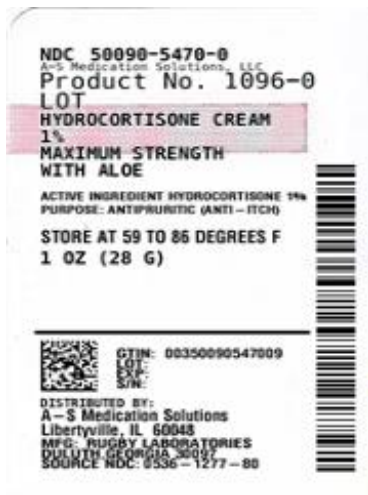
www.rugbylaboratories.com

HOW SUPPLIED

Product: 50090-5470

NDC: 50090-5470-0 28 g in a TUBE / 1 in a CARTON

RUGBY HYDROCORTISONE WITH ALOE (HYDROCORTISONE) CREAM



RUGBY HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50090-5470(NDC:0536-1277)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.01 g in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CARBOXYPOLYMETHYLENE (UNII: 0A5MM307FC)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DMDM HYDANTOIN (UNII: BYR0546TOW)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TROLAMINE (UNII: 9O3K93S3TK)	
EDETATE TRISODIUM (UNII: 420IP921MB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50090-5470-0	1 in 1 CARTON	02/24/2021	
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	01/14/2020	

Labeler - A-S Medication Solutions (830016429)

Establishment

Name	Address	ID/FEI	Business Operations
A-S Medication Solutions		830016429	RELABEL(50090-5470)

Revised: 2/2023

A-S Medication Solutions