

HYDROSKIN- hydrocortisone lotion
Rugby Laboratories

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 HydroSKIN 1% Hydrocortizone Lotion 4 oz (7997)

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- for temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - cosmetics
 - insect bites
 - detergents
 - jewelry
 - seborrheic dermatitis
 - soaps
 - 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

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

When using this product

- avoid contact with the eyes
- do not begin use of any other hydrocortisone product unless you have asked a doctor
- for external anal itching do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, consult a doctor promptly.
- do not put this product 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 occur again within a few days. Do not begin use of 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

shake well before use

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:

- Ask 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 with external anal itching: ask a doctor

Inactive ingredients

benzyl alcohol, cetyl alcohol, glycerin, glyceryl monostearate, isopropyl palmitate, lactic acid, polysorbate 60, propylene glycol, purified water, sorbitan monostearate, sorbitol solution 70%, stearyl alcohol, white wax.

Questions or comments?

1-800-645-2158

Package/Label Principal Display Panel

Rugby Laboratories

Maximum Strength

HydroSKIN

hydrocortisone 1% Lotion

Drug Facts (continued)**Directions**

- shake well before use
- adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years: ask a doctor

For external anal itching:

- when practical, clean the affected area with mild soap and warm water and rinse thoroughly
- gently dry by patting or blotting with toilet tissue or soft cloth before application of this product
- children under 12 years: ask a doctor

Other information ■ store at room temperature ■ Lot No. & Exp. Date: bottom of container

Inactive ingredients benzyl alcohol, cetyl alcohol, glycerin, glyceryl monostearate, isopropyl palmitate, lactic acid, polysorbate 60, propylene glycol, purified water, sorbitan monostearate, sorbitol solution 70%, stearyl alcohol, white wax

Questions or Comments?
1-800-645-2158

Rev. 06/15
R-110
Re-Order No. 370430
Made in Korea

Distributed by:
Rugby Laboratories
31778 Enterprise Drive Livonia, MI 48150
www.rugbylaboratories.com



NDC 0536-1079-97

Rugby®**MAXIMUM STRENGTH****Hydro SKIN****1% Hydrocortisone Lotion****Relief from:**

- Minor Skin Irritations
- Insect Bites
- Inflammation and Rashes
- Poison Ivy

Net contents 4 fl oz (118 mL)

Drug Facts

Active ingredient	Purpose
Hydrocortisone 1%	Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to eczema, insect bites, poison ivy, poison oak, poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, and psoriasis
- for external genital, feminine and anal itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use for the treatment of diaper rash.

Ask a doctor before use if you have a vaginal discharge (for external feminine itching)

When using this product

- avoid contact with the eyes
- for external anal itching, do not use more than directed. In case of bleeding, consult a doctor promptly.
- do not insert lotion into rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days. Do not begin use of 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. ►

HYDROSKIN

hydrocortisone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1079
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
WHITE WAX (UNII: 7G1J5DA97F)	
LACTIC ACID, L- (UNII: F9S9FFU82N)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1079-97	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	08/25/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/25/2015	

Labeler - Rugby Laboratories (079246066)

Revised: 12/2017

Rugby Laboratories