

RUGBY HYDROSKIN- hydrocortisone cream

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 Cream 1 oz (6995)

Active ingredient	Purpose
Hydrocortisone 1%.....	Anti-itch

Uses for the 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 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 in the genital area if you have a vaginal discharge. Consult a doctor.

Do not use for the treatment of diaper rash. Consult a doctor.

- when using this product

Avoid contact with the eyes. Do not use more than directed unless told to do so by a doctor.

Do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop using this product and ask a doctor

- if condition worsens, or if 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.
- if rectal bleeding occurs.

Do not use this product and ask a doctor

- if you have a vaginal discharge
- before treating diaper rash
- before using on children under 2 years of age

Keep this and all drugs out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

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

Directions

For itching of skin irritation, inflammation, and rashes:

- for 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 and genital itching, adults:

- 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 applying
- 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 20°-25°C (68°-77°F)
- Lot No. and Exp. Date: see box or see crimp of tube
- Retain carton for complete product labeling

Inactive ingredients

Aloe Vera Gel, Butylated Hydroxytoluene, Cetanol, Liquid Paraffin, Methylparaben, Polyoxyethylene Cetyether, Propylene Glycol, Propylparaben, Purified Water, Sorbitan Monostearate, Stearyl Alcohol

Distributed by:

Rugby Laboratories

31778 Enterprise Drive

Livonia, MI 48150 USA

www.rugbylaboratories.com

Made in Korea

Rugby®

Compare to Active Ingredient
in Cortizone 10®*

**NEW
FORMULA**

HydroSKIN

1% Hydrocortisone Cream

with Healing Aloe

Relief from:

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

Rugby®

NDC 0536-1069-95

MAXIMUM STRENGTH

HydroSKIN

1% Hydrocortisone Cream

with Healing Aloe

Net wt. 1 oz (28 g)

Rugby®

MAXIMUM STRENGTH
HydroSKIN
1% Hydrocortisone Cream



Distributed by:
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31778 Enterprise Drive
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Rev. 04/15
R-110
Re-Order No. 370431
Made in Korea

*Rugby Laboratories is not affiliated with the
owner of the trademark Cortizone-10®.

LOT & EXP

Drug Facts

Active ingredient
Hydrocortisone 1%
Anti-Itch

Purpose
Relief of skin irritation, inflammation, and rashes.

Directions
For adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily.
For children under 2 years of age: consult a doctor.
For external and general itching, adults:
When practical, clean the affected area with mild soap and warm water.
Apply to affected area not more than 3 to 4 times daily.
Apply gently by patting or blotting with toilet tissue or soft cloth before applying.
Apply to affected area not more than 3 to 4 times daily.
Apply to affected area not more than 3 to 4 times daily.

Warnings
For external use only.
Do not use in the genital area if you have a vaginal discharge; consult a doctor.
When using this product:
Do not use more than directed unless told to do so by a doctor.
Avoid contact with the eyes.
Do not put directly into the rectum by using fingers or any mechanical device or applicator.
Stop use and ask a doctor if:
Irritation worsens, or if 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.
If rectal bleeding occurs.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Other information
Store at 20°-25°C (68°-77°F). See Lot No. & Exp. Date on box or see crimp of tube.
Return carton for complete product labeling.

Inactive ingredients
aloe vera gel, butylated hydroxytoluene, cetanol, liquid paraffin, methylparaben, polyoxyethylene sorbitol, polyoxyethylene glycol, propylparaben, purified water, sorbitan monostearate, stearyl alcohol.

Questions or Comments?
1-800-846-2158

RUGBY HYDROSKIN

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1069
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1069-95	1 in 1 CARTON	07/15/2015	
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	07/15/2015	

Labeler - Rugby Laboratories (079246066)

Revised: 12/2017

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