

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.

Rite Aid Anti-Itch Cream Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
- eczema
- psoriasis
- poison ivy, oak, sumac
- insect bites
- detergents
- jewelry
- cosmetics
- soaps
- seborrheic dermatitis
- temporarily relieves external anal and genital 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.
- in the genital area if you have a vaginal discharge. Ask a doctor.

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 cream 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor

Keep out of reach of children.

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

Directions

- for itching of skin irritation, 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: do not use, ask 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 a soft cloth before applying
- apply to affected area not more than 3 to 4 times daily
- children under 12 years of age: ask a doctor

Other information

- store at 15°-30°C (59°-86°F)
- see box or crimp of tube for lot number and expiration date

Inactive ingredients

emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, sorbitol solution,
Preservative: benzyl alcohol

Questions or comments?

1-800-645-2158

Principal Display Panel

Maximum Strength

Anti-Itch Cream

1% Hydrocortisone Anti-Itch Cream

ODORLESS CREAM FOR RELIEF OF

Skin Irritations, Inflammation and Rashes

Due to • Insect Bites • Eczema
• Poison Ivy, Oak, Sumac
• External Genital, Feminine and Anal Itch
• Seborrheic Dermatitis, Psoriasis



COMPARE TO ACTIVE INGREDIENT IN CORTIZONE-10®

MAXIMUM STRENGTH Anti-itch/Antipruritic

Rugby HydroSKIN®
Hydrocortisone Cream USP, 1%

NDC 0536-5108-95

MAXIMUM STRENGTH Anti-itch/Antipruritic

Rugby HydroSKIN®
Hydrocortisone Cream USP, 1%
Net Wt. 1 oz (28 g)

CREAM

Rugby

SEE ACTION GUARANTEED FOR YOUR MONEY BACK!

Drug Facts	
Active ingredient	Purpose
Hydrocortisone USP, 1%	Anti-itch
Uses	
<ul style="list-style-type: none"> 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, psoriasis 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 the treatment of diaper rash	
Ask a doctor before use if you have a vaginal discharge (for external feminine itching)	
When using this product	
<ul style="list-style-type: none"> 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 cream into rectum by using fingers or any mechanical device or applicator 	
Stop use and ask a doctor if	
<ul style="list-style-type: none"> condition worsens symptoms last 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.	
Drug Facts (continued)	
Directions	
<ul style="list-style-type: none"> 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 	
adults: For external anal itching:	
<ul style="list-style-type: none"> 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 a soft cloth before application of cream 	
children under 12 years: ask a doctor	
Other information	
<ul style="list-style-type: none"> store at room temperature 15°- 30°C (59°- 86°F) see box or crimp of tube for lot number and expiration date 	
Inactive ingredients	
emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, sorbitol solution. Preservative: benzyl alcohol	
Questions or comments?	
call 1-800-645-2158, 9 am - 5 pm EST, Monday - Friday	

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Duluth, Georgia 30097

Rugby

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HYDROSKIN			
hydrocortisone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-5108
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LACTIC ACID (UNII: 33X04XA5AT)	
SORBITOL (UNII: 506T60A25R)	

Product Characteristics

Color	WHITE (Off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-5108-95	1 in 1 CARTON		
1		28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/29/2012	

Labeler - Rugby Laboratories (191427277)

Revised: 1/2013

Rugby Laboratories