HYDRO SKIN- 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.

Amerisource Bergen Anti-Itch Lotion Drug Facts

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
- 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 eves
- 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:

• do not use. 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

benzyll alcohol, emulsifying wax, glycerin, isopropyl palmitate, lactic acid, purified water, sorbitol 70% solution

Questions or comments?

1-800-645-2158

Package/Label Principal Display Panel

Rugby Laboratories

Maximum Strength

Anti-Itch Lotion

hydrocortisone 1%



HYDRO SKIN

hydrocortisone lotion

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:0536-5105	
Route of Administration	TOPICAL	DEA Sche dule		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (HYDROCORTISONE)	HYDROCORTISONE	1g in 1 mL

Inactive Ingredients			
Ingredient Name	Strength		
WATER			
BENZYL ALCOHOL			
GLYCERIN			
ISOPROPYL PALMITATE			
LACTIC ACID			
SORBITOL			

Packaging				
# Item Code	Package Description	Marketing Start Date	Marketing End Date	
1 NDC:0536-5105-97	118 mL in 1 BOTTLE			

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)

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