

HYDROCORTISONE - hydrocortisone cream

Morales Distributors Inc

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.

Hydrocortisone

Active ingredient

Hydrocortisone 1.0 percent

Purpose

Anti-Itch

Uses

temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to

- eczema
- psoriasis
- seborrheic dermatitis
- poison ivy, oak, sumac
- insect bites
- soaps and detergents
- cosmetics
- jewelry
- external feminine and anal itching

Other uses of this product: ask a doctor

Warnings

For external use only

Do not use

- in or near the eyes
- by putting directly into the rectum by using fingers or any mechanical device or applicator
- for external feminine itching if you have a vaginal discharge
- for diaper rash; ask a doctor

Ask a doctor or pharmacist

before use if you are using any other hydrocortisone product

When using this product

for external anal itching, do not exceed recommended daily dosage unless directed by a doctor

Stop use and ask a doctor if

- condition worsens or does not improve within 7 days
- symptoms clear up and return within a few days
- rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control

Directions

- apply to affected area not more than 3 to 4 times daily
- for external anal itching: when practical, clean area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product
- children under 2 years, or children under 12 years with external anal itching, do not use, ask a doctor

Other information

store at room temperature, protect from freezing

Inactive ingredients

butylated hydroxytoluene, cetyl alcohol, glycerin, glyceryl monostearate, isopropyl myristate, methylparaben, propylparaben, purified water, squalane, and stearic acid

Principal Label

NDC NO. 53210-1002-0

Compare to maximum strength Cortaid(R) active ingredient

Maximum Strength

FAST RELIEF

plus itching plus redness

Anti-Itch Cream for Skin Irritations

Relieves Itching and Redness Fast

Hydrocortisone 1 percent Cream

NET 1oz(28.3g)

Exclusively distributed by:

Morales Distributors, Inc

Mayaguez, P.R. 00682

This product is not manufactured or distributed by Pharmacia Consumer Healthcare, owner of the registered trademark Cortaid.(R)

Made in Korea



NDC NO. 53210-1002-0

Compare to maximum strength Cortaid® active ingredient*



MAXIMUM STRENGTH
FAST RELIEF
+ Itching + Redness
Anti-Itch Cream for Skin Irritations

Relieves Itching and Redness Fast!

MAXIMUM STRENGTH

Hydrocortisone 1% Cream
Relieves Itching and Redness Fast!

NET 1 oz(28.3g)

LOT & EXP

MAXIMUM STRENGTH
Hydrocortisone
Relieves Itching and Redness Fast!



Exclusively distributed by:
Morales Distributors, Inc
Mayaguez, P.R. 00682



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Hydrocortisone

Relieves Itching and Redness Fast!

Drug Facts		Drug Facts(continued)
Active ingredient(in each gram) Hydrocortisone1.0%.....	Purpose Anti-Itch	Keep out of reach of children. If swallowed, get medical help or contact a Poison Control
Uses temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to: ■eczema ■ psoriasis ■ seborrheic dermatitis ■poison ivy, oak, sumac ■ insect bites ■soaps and detergents ■ cosmetics ■ jewelry ■ external feminine and anal itching Other uses of this product: ask a doctor		Directions ■ apply to affected area not more than 3 to 4 times daily ■ for external anal itching: when practical, clean area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product ■ children under 2 years, or children under 12 years with external anal itching: do not use, ask a doctor
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Made in Korea

MAXIMUM STRENGTH



1% Cream

Hydrocortisone
Relieves Itching and Redness Fast!

NET 1 oz (28.3g)

Active ingredient Hydrocortisone1.0%

Uses temporarily relieves itching associated with minor skin irritation, inflammation and rashes due to: ■eczema ■ psoriasis ■ seborrheic dermatitis ■poison ivy, oak, sumac ■ insect bites ■ soaps and detergents ■ cosmetics ■ jewelry ■ external feminine and anal itching ; Other uses of this product: ask a doctor

Warnings **For external use only- Do not use** ■ in or near the eyes ■ by putting directly into the rectum by using fingers or any mechanical device or applicator ■ for external feminine itching if you have a vaginal discharge ■ for diaper rash ; ask a doctor

Ask a doctor or pharmacist before use if you are using any other hydrocortisone product

When using this product for external anal itching, do not exceed recommended daily dosage unless directed by a doctor

Stop use and ask a doctor if ■ condition worsens or does not improve within 7 days ■ symptoms clear up and return within a few days ■ rectal bleeding occurs

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions ■ apply to affected area not more than 3 to 4 times daily ■ for external anal itching: when practical, clean area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product ■ children under 2 years, or children under 12 years with external anal itching: do not use, ask a doctor

Other information ■ store at room temperature, protect from freezing

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HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:53210-1002
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53210-1002-0	1 in 1 BOX		
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	09/25/2012	

Labeler - Morales Distributors Inc (127151731)