

HYDROCORTISONE- hydrocortisone cream
Rebel Distributors Corp

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.

Perrigo Hydrocortisone Cream 1% 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
- 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

Keep out of reach of children.

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

Directions

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

Other information

- store at 20°-25°C (68°-77°F)

Inactive ingredients

aloe vera gel, cetareth-20, cetaryl alcohol, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, purified water

Questions or comments?

1-800-719-9260

Principal Display Panel

Relieves Itching and Redness Fast

Maximum Strength

Helps Heal Rashes for Healthier Skin

Compare to Cortaid® active ingredient

Hydrocortisone Cream 1%

Maximum Strength Anti-Itch Cream

PHYSICIAN PARTNER_x
A DIVISION OF BEREL DISTRIBUTORS CORP

NDC 42254-136-01

Hydrocortisone 1%
1oz Cream

Each tube contains: Hydrocortisone 1%
(Anti-itch)

See box

Product ID: SH013601

Dist. By: Perrigo Allegan, MI 49010

Distributed by: Physician Partner, Thousand Oaks, CA 91320 www.physicianpartner.com
Store at controlled room temperature 15°-30°C (59°-86°F) Keep medication out of the reach of children.

Peel

Hydrocortisone 1%
1oz Cream
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-136-01 AWP: \$7.20

Rx# Master

Peel

Hydrocortisone 1%
1oz Cream
Lot #: 000000 Exp. Date: 00/00/00
NDC 42254-136-01 AWP: \$7.20

Rx# Master

HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42254-136(NDC:45802-438)
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)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

METHYLPARABEN (UNII: A2I8C7H9T)

WATER (UNII: 059QF0K00R)

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42254-136-01	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	04/13/2011	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 3/2012

Rebel Distributors Corp