# 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.

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## 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, ceteareth-20, cetearyl 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

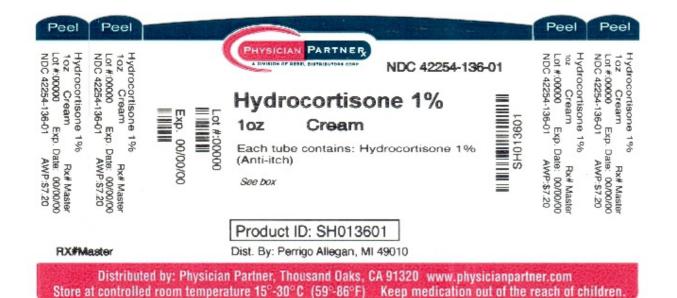
Maximum Strength

Helps Heal Rashes for Healthier Skin

Compare to Cortaid® active ingredient

Hydrocortisone Cream 1%

Maximum Strength Anti-Itch Cream



## **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		
HYDRO CORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g		

Inactive Ingredients				
Ingredient Name	Strength			
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)				
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528 SWUY)				
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)				
CETYL PALMITATE (UNII: 5ZA2S6B08X)				
GLYCERIN (UNII: PDC6 A3C0 OX)				
ISOPROPYL MYRISTATE (UNII: 0 RE8 K4LNJS)				

METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	

Product Characteristics				
Color	WHITE	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				

P	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