

HYDROCORTISONE- hydrocortisone cream
Central Texas Community Health Centers

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 - 28 g Tube Label

CommUnityCare Federally Qualified Health Centers

HYDROCORTISONE

1% CR 28g

Date:

Name:

Dr.

USE AS DIRECTED.

1/1/01

123456

HYDROCORTISONE 1% CRM 30G NDC 76413-339-28

Batch: 123456
Lot: 123456
Exp: 1/1/01
PERRIGO

Federal law prohibits the transfer of this drug to any other person than the patient for whom prescribed.

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HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76413-339(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)	

METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-339-28	28 g in 1 TUBE; Type 0: Not a Combination Product	04/13/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/13/2011	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-339) , RELABEL(76413-339)