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.

Hydrocortisone

Active ingredient

Hydrocortisone 1.0%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:

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

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. Consult a doctor.
- for external genital itching if you have vaginal discharge. Consult a doctor.

When using this product

- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly 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, and do not begin use of any other hydrocortisone product unless you have asked a doctor

- rectal bleeding occurs

Keep out of reach of children.

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

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. Consult a doctor.

For external anal itching
- adults: when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly or 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: consult a doctor

Other information
- store at 15° to 30°C (59° to 86°F)
- lot number and expiration date: See crimp of tube or box

You may report serious side effects to: *130 Vintage Drive, Huntsville, AL 35811.*

Inactive ingredients

cetyl alcohol, diazolidinyl urea, isopropyl palmitate, mineral oil/lanolin alcohol, polysorbate 40, propylene glycol, propylene glycol monostearate, purified water, sorbic acid, sorbitan monopalmitate, stearyl alcohol, xanthan gum

Made in the **USA**
for Qualitest Pharmaceuticals
Huntsville, AL 35811

Rev. 5/15 R6
8265556 0534

PRINCIPAL DISPLAY PANEL - 28 g Tube Label

CommUnityCare Federally Qualified Health Centers

HYDROCORTISONE
1% CR 28g

Date:

Name:
Dr.

USE AS DIRECTED.

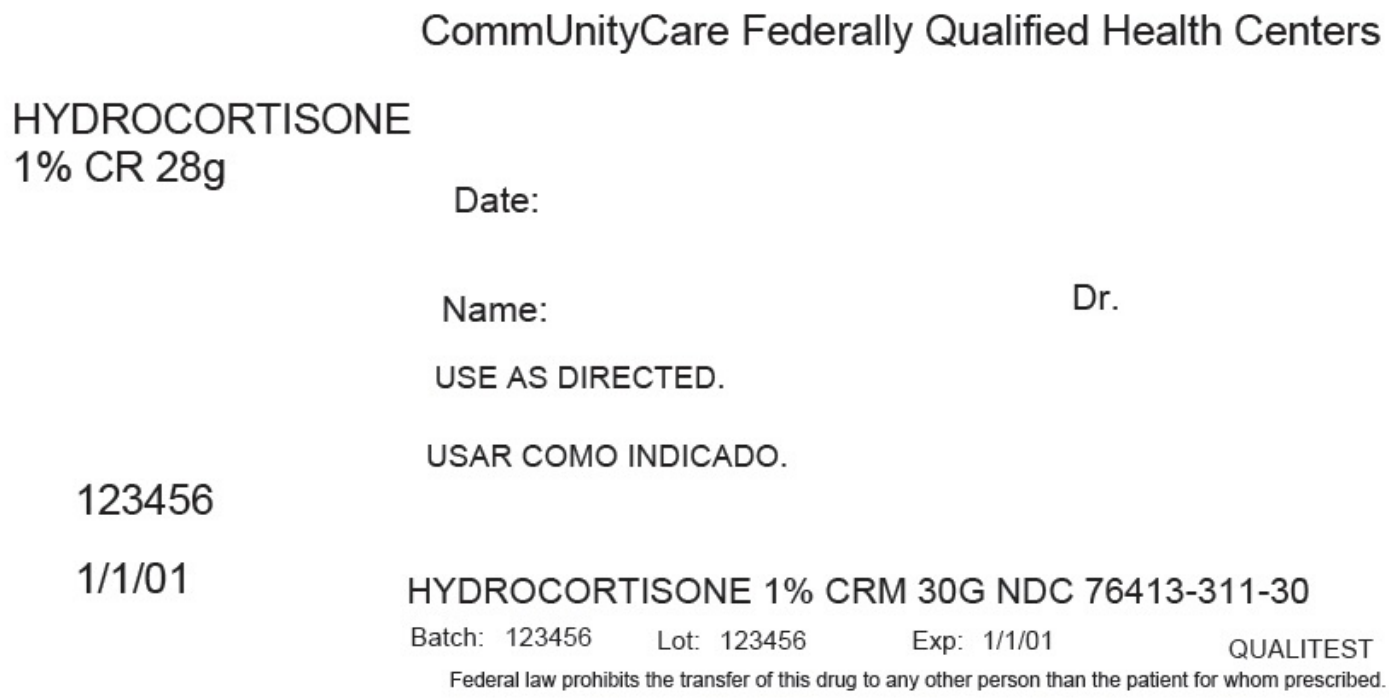
123456

1/1/01

HYDROCORTISONE 1% CRM 30G NDC 76413-311-30

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

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



HYDROCORTISONE

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:76413-311(NDC:0603-0535)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
CETYL ALCOHOL (UNII: 936JST6JCN)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
MINERAL OIL (UNII: T5L8T28FGP)	
LANOLIN ALCOHOLS (UNII: 884C3FA9HE)	

POLYSORBATE 40 (UNII: STI11B5A2X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLENE GLYCOL MONOSTEARATE (UNII: MZM1I680W0)	
WATER (UNII: 059QF0KO0R)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN MONOPALMITATE (UNII: 77K6Z421KU)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76413-311-30	1 in 1 CARTON	10/01/2001	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/01/2001	

Labeler - Central Texas Community Health Centers (079674019)

Establishment

Name	Address	ID/FEI	Business Operations
Central Texas Community Health Centers		079674019	REPACK(76413-311) , RELABEL(76413-311)

Revised: 4/2016 Central Texas Community Health Centers