

## **HYDROCORTISONE CREAM- hydrocortisone cream**

**Trifecta Pharmaceuticals USA**

*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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### **Hydrocortisone Cream 1%**

#### **Active Ingredient**

Hydrocortisone 1%

#### **Purpose**

Anti-Itch

#### **Uses**

Temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to:

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

Other uses of this product should be only under the advice and supervision of a doctor

#### **Keep out of reach of children**

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

#### **Warnings**

- for external use only
- avoid contact with eyes
- do not put this product into the rectum by using fingers or any mechanical device or applicator

#### **For External Anal Itching Users:**

- do not exceed the recommended daily dosage unless directed by a doctor
- in case of bleeding, consult a doctor promptly
- children under 12 years of age: consult a doctor

**Before using any medication, read all label directions. Keep this carton as it contains important information**

**Stop using this product and ask a doctor**

- in case of bleeding
- if condition worsens or if symptoms persist for more than 7 days or clear up and occur again within a few days
- before you begin using any other hydrocortisone product

**Do not use this product and ask a doctor**

- If you have a vaginal discharge
- before treating diaper rash
- before using on children under 2 years of age

**Directions**

- 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 applying
- adults and children 12 years of age and older, apply to the affected area not more than 3 to 4 times daily
- children under 12 years of age: do not use, consult a doctor

**Inactive Ingredients**

Aloe barbadensis leaf juice, ethylparaben, glycerin, glycerol monostearate, hexadecanol, mineral water, octadecanol, petrolatum, purified water, sodium dodecyl sulfate

**Other Information**

- to open; unscrew cap and pull tab to remove foil seal
- if seal has been broken, do not use this product. Return product to the store where you bought it
- store at controlled room temperature 15°-30°C (59°-86°F)
- see carton or tube crimp for lot number and expiration date

**Other Information**

Distributed By:

**Trifecta Pharmaceuticals USA™**

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL. 33301 USA

Product of PRC


**[www.trifecta-pharma.com](http://www.trifecta-pharma.com)**

1-888-296-9067

**Packaging**



INNER TUBE




# Hydrocortisone

## Cream 1%

ANTIPRURITIC (Anti-Itch)

NDC: 69396-028-01



Net Wt. 1 oz. (28.4g)

**Active Ingredient:**

**Hydrocortisone 1%:**

**Uses:** For temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:

- eczema • insect bites • poison ivy • poison oak • poison sumac
- sores • allergic dermatitis • contact dermatitis • jewelry • allergic dermatitis • allergic reactions • external hemorrhoids, genital and anal itching

One use 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 no vaginal discharge, consult a doctor.

**When using this product:** • avoid contact with the eyes. • do not begin the use of any other hydrocortisone product unless you have been consulted a doctor. • for external genital, feminine and anal itching do not exceed the recommended dosage. Under medical supervision, in case of bleeding, stop use, consult a doctor. • do not put this product into the rectum by enemas or any mechanical device in applicator. ►

**Maximum Strength**

**Stop using this product and ask a doctor if:** • conditions worsen • symptoms persist for more than 7 days or clear up and occur again within a few days. • duration of use of the product and do not longer use of any other hydrocortisone product unless directed by a doctor.

**Keep out of the reach of children.**

**First Aid:** If swallowed, consult a Poison Control Center immediately.

**Directions:** Adults and children 2 years and older: apply to affected skin areas 2 or 3 times daily.

**Children under 2 years of age:** do not use, consult a doctor.

**For external use and itching:**

- adults: when practical, cleanse the affected area with mild soap and water and thoroughly dry by patting (drying with towel) or use soft cloth when application of this product.
- children under 2 years of age or infants and young children: consult a doctor.

**Store Information:** store at controlled room temperature 20°-25°C (68°-77°F) in sealed containers. Avoid excessive humidity, moisture, perfume, water, carbon dioxide, etc.

**Produced by: Teleflex Pharmaceuticals USA®**

111 NE Third Avenue, Suite 1580 Ft. Lauderdale, FL 33301 USA | Product of PRC | [www.hydrocortisone.com](http://www.hydrocortisone.com)

## HYDROCORTISONE CREAM

hydrocortisone cream

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-028	
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	
ETHYLPARABEN (UNII: 14255EXE39)				
GLYCERIN (UNII: PDC6A3C0OX)				
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
STEARYL ALCOHOL (UNII: 2KR89I4HIY)				
PETROLATUM (UNII: 4T6H12BN9U)				
SODIUM LAURYL SULFATE (UNII: 368GB5141J)				
ALOE VERA LEAF (UNII: ZY81Z83H0X)				
CETYL ALCOHOL (UNII: 936JST6JCN)				
WATER (UNII: 059QF0KO0R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-028-01	1 in 1 BOX	04/07/2017	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-028-02	1 in 1 BOX	04/07/2017	
2		56 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	04/07/2017	

**Labeler** - Trifecta Pharmaceuticals USA (079424163)