

# **HYDROCORTISONE CREAM- hydrocortisone cream**

## **Trifecta Pharmaceuticals USA**

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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

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

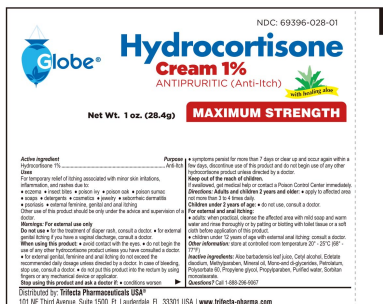
1-888-296-9067

## Package Label

## OUTSIDE BOX



# INNER TUBE

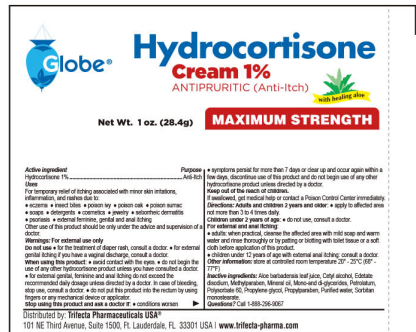


## Label

## OUTSIDE BOX



## INNER TUBE



# 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: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

## Inactive Ingredients

Ingredient Name	Strength
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
ETHYLPARABEN (UNII: 14255EXE39)	

## 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		

1		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		
3	NDC:69396-028-44	4 in 1 BOX	02/07/2024	
3		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
4	NDC:69396-028-33	3 in 1 BOX	02/28/2024	
4		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 Drug	M017	04/07/2017	

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

Revised: 2/2024

Trifecta Pharmaceuticals USA