

HYDROCORTISONE CREAM- hydrocortisone cream
Trifecta Pharmaceuticals USA

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

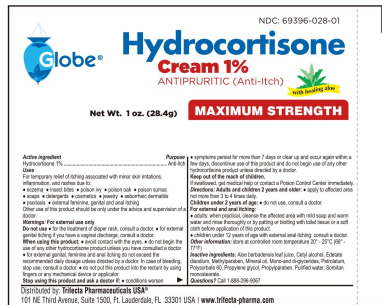
www.trifecta-pharma.com

1-888-296-9067

OUTSIDE BOX



INNER TUBE





Hydrocortisone

Cream 1%

ANTI-PRURITIC (Anti-Itch)



Net Wt. 1 oz. (28.4g)

MAXIMUM STRENGTH

Active ingredient: Hydrocortisone 1%
Purpose: For temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:
 • eczema • insect bites • exposure to poison oak • poison sumac
 • sunburn • allergic reactions • dermatitis • allergy • eczematous dermatitis
 • psoriasis • contact dermatitis • genital and anal itching
 • other causes of the product's indications 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 a major discharge, consult a doctor.
 When using this product, avoid contact with the eyes. Do not begin the use of this hydrocortisone product unless you have consulted your doctor.
 • In normal practice, irritation and/or burning do not exceed the recommended daily dosage unless directed by a doctor. In case of burning, stop use, consult a doctor, do not use the product, and the reaction by using ingested or any mechanical device or appliance.
 Stop using the product and see a doctor if a condition worsens.

Precautions: • Symptoms persist for more than 7 days or clear up and occur again within a few days, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor.
 • If you experience relief of itching associated with minor skin irritations, inflammation, and rashes due to:
 • eczema • insect bites • exposure to poison oak • poison sumac • sunburn • allergic reactions • dermatitis • allergy • eczematous dermatitis • psoriasis • contact dermatitis • genital and anal itching • other causes of the product's indications only under the advice and supervision of a doctor.
 • Do not use for the treatment of diaper rash. Consult a doctor. For external genital itching if you have a major discharge, consult a doctor.
 • When using this product, avoid contact with the eyes. Do not begin the use of this hydrocortisone product unless you have consulted your doctor.
 • In normal practice, irritation and/or burning do not exceed the recommended daily dosage unless directed by a doctor. In case of burning, stop use, consult a doctor, do not use the product, and the reaction by using ingested or any mechanical device or appliance.
 Stop using the product and see a doctor if a condition worsens.

Directions: Apply and rub gently 2-3 times daily. Apply to affected area not more than 3-4 times daily. Continue under medical supervision. Do not use, consult a doctor, if irritation and/or burning.
 • Adults, when practical, cleanse the affected area with mild soap and warm water and cover thoroughly or by padding or taping with loose tissue or a soft cloth before application of this product.
 • Pediatric use: 12 years of age with external anal itching, consult a doctor.
 Other information: Store at controlled room temperature 20°-25°C (68°-77°).

Active ingredients: Also contains: Aluminum Chloride, Chlorhexidine, Menthol, Methylparaben, Mineral Oil, Stearic Acid, Stearoyl Alcohol, Polyethylene Glycol, Propylene Glycol, Propylparaben, Purified Water, Sorbitan Monooleate.
 Questions? Call 1-800-268-0007

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Package Label

OUTSIDE BOX



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	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)				
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)				
GLYCERIN (UNII: PDC6A3C0OX)				
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 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: 6/2024

Trifecta Pharmaceuticals USA