

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.

Hydrocortisone Cream 1%

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Uses

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

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

Other use 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

Stop using this product and ask a doctor

- Conditions worsen

- 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.

When using this product

When using this product

- avoid contact with the eyes
- do not begin the use of any other hydrocortisone product unless you have consulted a doctor
- for external genital, feminine and anal itching do not exceed the recommended daily dosage unless directed by a doctor. In case of bleeding, stop use, consult a doctor.
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

Do not use

Do not Use

- for the treatment of diaper rash, consult a doctor.
- for external genital itching if you have a vaginal discharge, consult a doctor.

Directions

Adults and Children 2 years 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 and 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 and anal itching: Consult a doctor.

Inactive Ingredients

Aloe barbadensis leaf juice, Cetyl alcohol, Dimethicone, EDTA, Ethylparaben, Ginger Oil, glycerin, Glycerol Stearate, Maltodextrin, Methyl gluceth-20, Methylparaben, Methylpentadecane, petrolatum, 2-Phenoxyethanol, Polysorbate 80, Propylene Glycol, purified water, Stearic Acid, Trisodium citrate dihydrate, Vitamin E.

Other Information

- store at controlled room temperature 20°- 25°C (68°-77°F)

Questions ?

Call 1-888-296-9067

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

This product is not manufactured or distributed by Chattem, Inc. distributor of Cortizone-10.

Package Label

JAR

COMPARE TO CORTIZONE-10® ACTIVE INGREDIENT*
NDC: 69396-096-16

 **Hydrocortisone Cream 1%**
with healing oils

ANTIPRURITIC (Anti-Itch)
Effective Itch & Rash Relief For
Eczema, Seborrheic Dermatitis, Psoriasis, Insect Bites
Net Wt. 16 oz. (1 lb) (454g)

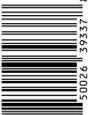
MAXIMUM STRENGTH

Drug Facts	Purpose
Active ingredient Hydrocortisone 1% For temporary relief of itching associated with minor skin irritations, inflammation and rashes due to: • insect bites • allergic reactions • poison oak • poison ivy • poison sumac • eczema • dermatitis • contact • jewelry • allergic dermatitis • psoriasis • external hemorrhoids, genital and anal itching *This product is not intended for use under the direct and supervision of a doctor.	Hydrocortisone 1% (0.01%) For temporary relief of itching associated with minor skin irritations, inflammation and rashes due to: • insect bites • allergic reactions • poison oak • poison ivy • poison sumac • eczema • dermatitis • contact • jewelry • allergic dermatitis • psoriasis • external hemorrhoids, genital and anal itching *This product is not intended for use under the direct and supervision of a doctor.
Warnings For external use only • For the treatment of diaper rash, consult a doctor. • For external genital itching if you have a vaginal discharge, consult a doctor. When using this product • Do not use with any other hydrocortisone product unless you have consulted a doctor. • For external genital, hemorrhoid and anal itching do not exceed the recommended frequency of use. • Do not put this product into the rectum by using fingers or any bleeding, stop use, consult a doctor. Stop using this product and ask a doctor if • conditions worsen • itching means that 7 days of daily use and each application within a few days, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor. • you experience a rash, hives, or other allergic reaction. • If swallowed, get medical help or contact a Poison Control Center immediately.	
Directions • Apply to affected area not more than 3 to 4 times daily. • Children under 2 years of age For external and anal itching: • Adults: when practical, cleanse the affected area with mild soap and water, pat dry, then apply a thin layer of cream to the affected area. Rub in until the cream is absorbed. • Children under 12 years of age with external anal itching, consult a doctor.	
Other information Store at controlled room temperature 20° -25° C. (68° - 77° F).	
Inactive ingredients Cetyl alcohol, Dexamethasone, EDTA, Ethylparaben, Glycerin, Glyceryl oleate, Methylparaben, Methyl glucose-20-Methylparaben, Methylparaben, Phenacetin, Polyethylene Glycol 400, Potassium Hydroxide, Purified Water, Stearic acid, Triethylamine, Vitamin E	
Questions? Call: 1-888-296-9067	

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www.trifecta-pharma.com

LOT:
EXP:



8 50026 59337 1 8



HYDROCORTISONE CREAM

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-096
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
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
EDETIC ACID (UNII: 9G34HU7RV0)	
GINGER OIL (UNII: SAS9Z1SVUK)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
3-METHYLPENTADECANE (UNII: X64R3JC095)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
ETHYLPARABEN (UNII: 14255EXE39)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
.ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-096-16	454 g in 1 JAR; Type 0: Not a Combination Product	01/13/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	01/13/2022	

