

HYDROCORTISONE 1%- hydrocortisone cream
Chain Drug Marketing Association Inc.

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.

Quality Choice Hydrocortisone Cream 1%

MAXIMUM STRENGTH

DRUG FACTS

Active ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Keep out of the reach of children.

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

Uses

For temporary relief of 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 feminine genital and anal itching

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 a diaper rash, consult with doctor

For external genital itching if you have a vaginal discharge, consult doctor

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 and consult a doctor.
- do not put this product into the rectum by using fingers or any medicated device or applicator.

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, discontinue use of this product and do not begin use of any other hydrocortisone product unless directed by a doctor.

Directions

Adults and children 2 years of age and older: apply to the 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 anal itching: consult a doctor.

Inactive ingredients

Cetyl alcohol, Edetate disodium, Glyceryl monostearate, Methylparaben, Mineral Oil, Polysorbate 60, Propylene glycol, Propylparaben, Purified Water, Petrolatum, Sorbitan monostearate

Other information

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

Distributed by: CDMA, Inc.

43157 W 9 Mile Rd.

Novi, MI. 48375

www.qualitychoice.com

Product of PRC

Questions: 800-935-2362

This product is not manufactured or distributed by Valeant Pharmaceuticals North America, Inc. distributor of Cortaid.

OUTSIDE BOX

NDC 63868-689-01



*Compare to the active ingredients in CORTAID®

1% Hydrocortisone

Maximum Strength

Temporary Relief of:
Eczema | Poison Ivy, Oak, and Sumac | Insect Bites | Psoriasis | Dermatitis

Effective Relief Of Itches & Rashes Due To:
Eczema • Seborrheic Dermatitis • Psoriasis • Insect Bites
Poison Ivy, Oak, and Sumac • External Feminine, Genital and Anal Itching
Soaps • Cosmetics • Detergents • and more



1% Hydrocortisone

Maximum Strength

Temporary Relief of:
Eczema | Poison Ivy, Oak, and Sumac | Insect Bites | Psoriasis | Dermatitis

1 oz (Net Wt 28.3 g)



1% Hydrocortisone
Maximum Strength

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 Distributed by C.D.M.A., Inc.®
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Product of PRC

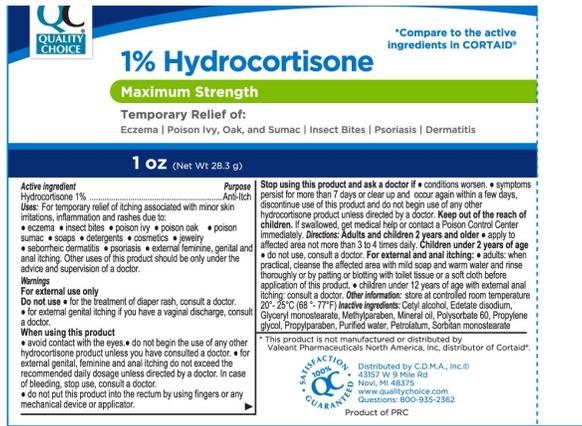


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LOT:
EXP:

<p>DRUG FACTS (continued)</p> <p>Stop using this product and ask a doctor if</p> <ul style="list-style-type: none"> • 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. • conditions worsen. <p>Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.</p> <p>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 bathing 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.</p> <p>Other information store at controlled room temperature 20°-25°C (68°-77°F)</p> <p>Inactive ingredients Propylparaben, Purified water, Purified water, Petrolatum, Sorbitan monostearate, Methylparaben, Mineral oil, Polysorbate 60, Propylene glycol, Cetyl alcohol, Edetate disodium, Glycerin, Glyceryl monostearate.</p>	<p>DRUG FACTS</p> <p>Active ingredient Hydrocortisone 1% Purpose Anti-itch</p> <p>Uses For temporary relief of itching associated with minor skin irritations, inflammation and rashes due to: • psoriasis • insect bites • poison ivy • poison oak • smac • soaps • detergents • cosmetics • jewelry • seborrheic dermatitis • psoriasis • external feminine, genital and anal itching Other uses of this product should be only under the advice and supervision of a doctor.</p> <p>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 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 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.</p>
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INNER TUBE



HYDROCORTISONE 1%

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-689
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
PETROLATUM (UNII: 4T6H12BN9U)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-689-01	1 in 1 BOX	12/12/2019	
1		28.3 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	12/12/2019	

Labeler - Chain Drug Marketing Association Inc. (011920774)**Registrant** - Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 3/2023

Chain Drug Marketing Association Inc.