

ANTI-ITCH WITH ALOE- hydrocortisone 1% 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 Anti-Itch Cream with Aloe

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

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

- insect bites
- eczema
- poison ivy
- poison oak
- poison sumac
- 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.

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.

Stop use 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.

Keep out of the reach of children

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

Other information

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

Inactive Ingredients

Aloe Vera (Aloe Barbadensis) leaf juice, Cetostearyl alcohol, Edatate Disodium, Glyceryl monostearate, Methylparaben, Mineral Oil, White Petrolatum, Propylene glycol, Purified Water, Sorbitan Monostearate, Polysorbate 60

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 the 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.

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 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.

Distributed By

Distributed By CDMA Inc.

43157 W 9 Mile Rd.

Novi, MI. 48375


www.qualitychoice.com

Questions: 800-935-2362

Product PRC

Packaging

OUTSIDE BOX



NDC 63868-688-01


Compare to the active ingredients in CORTIZONE-10

Anti-Itch Cream with Aloe

1% Hydrocortisone

Maximum Strength


Temporary Relief of:
Skin Irritation | Inflammation & Redness | Rashes | Insect Bites | Eczema & Psoriasis



Anti-Itch Cream with Aloe


1% Hydrocortisone

Maximum Strength




1 oz (Net Wt. 28.3 g)

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



Distributed by C.D.M.A., Inc.®
43157 W 9 Mile Rd
Novi, MI 48375
www.qualitychoice.com
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Product of PRC



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LOT:
EXP:

<p>DRUG FACTS (continued)</p> <p>Purpose Anti-Itch Hydrocortisone 1% Active Ingredient</p> <p>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 • soaps • detergents • cosmetics • jewelry • seborrheic dermatitis • psoriasis • external feminine, genital and anal itching</p> <p>Warnings 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. Stop using this product and ask a doctor if • conditions worsen</p>	<p>DRUG FACTS</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 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.</p> <p>Other information store at controlled room temperature 20° - 25°C (68° - 77°F)</p> <p>Inactive ingredients Aloe barbadensis leaf juice, Cetearyl alcohol, Edetate disodium, Glycol monostearate, Methylparaben, Mineral oil, monostearate, White petrolatum</p>
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Anti-Itch Cream with Aloe

INNER TUBE



Compare to the active ingredients in CORTIZONE-10



ANTI-ITCH WITH ALOE

hydrocortisone 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-688
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
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
PETROLATUM (UNII: 4T6H12BN9U)	
MINERAL OIL (UNII: T5L8T28FGP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-688-01	1 in 1 BOX	08/13/2020	
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	08/13/2020	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA, LLC. (079424163)

Revised: 5/2023

Chain Drug Marketing Association Inc.