# 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.

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#### 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 analitching 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 ithcing consult a doctor.

# **Distributed By**

Distributed By CDMA Inc.

43157 W 9 Mile Rd.

Novi, MI. 48375

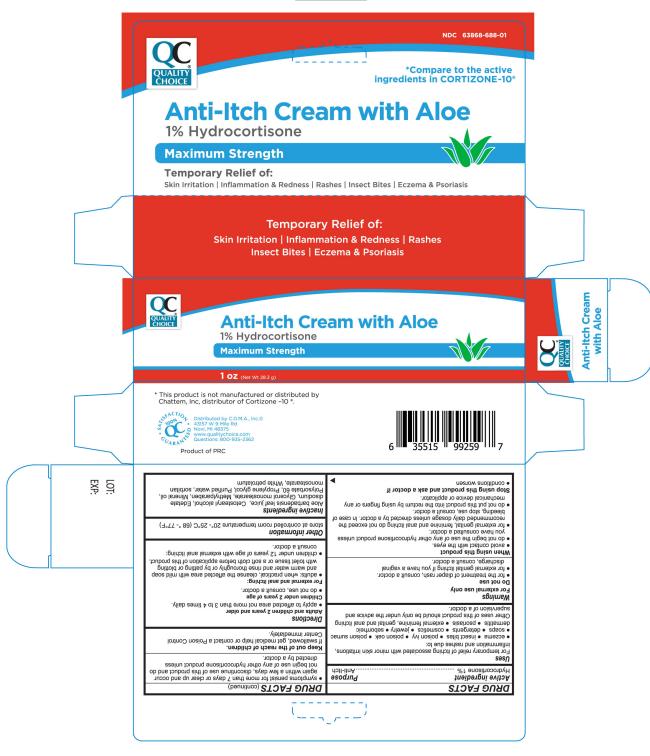
www.qualitychoice.com

Questions: 800-935-2362

**Product PRC** 

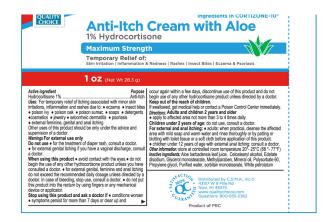
#### **Packaging**

#### **OUTSIDE BOX**



#### **INNER TUBE**





### **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 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: 2300U9XXE4)			

P	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.