

HYDROCORTISONE- hydrocortisone 1% cream
Pharmacy Value Alliance LLC

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.

Premier Value Hydrocortisone Cream 1%

Drug Facts

Active Ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Keep out of 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
- Insect bites
- 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

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
- 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 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.

Other Information

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

Inactive Ingredients

Aloe Barbadensis leaf juice, Cetostearyl alcohol, Edtate disodium, Glyceryl monostearate, Methylparaben, Mineral Oil, Polysorbate 60, Propylene Glycol, Purified Water, Sorbitan Monostearate, White Petrolatum

Questions

Call 1-866-923-4914

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Other Information

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

Distributed By:

Pharmacy Value Alliance, LLC.

407 East Lancaster Avenue

Wayne, PA. 19087

Product of PRC

Packaging

OUTSIDE BOX



DRUG FACTS	DRUG FACTS (continued)
Active ingredient Hydrocortisone 1% Anti-Itch	Purpose 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. 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 ■ insect bites ■ poison ivy ■ poison oak ■ poison sumac ■ soaps ■ detergents ■ cosmetics ■ jewelry ■ external feminine dermatitis ■ psoriasis	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 soft cloth before application of this product.
Warnings For external use only Other uses of this product should be 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 vaginal discharge; consult a doctor.

INSIDE TUBE



HYDROCORTISONE

hydrocortisone 1% cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-529
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
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	

CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-529-01	1 in 1 BOX	01/09/2020	
1		28 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	01/09/2020	

Labeler - Pharmacy Value Alliance LLC (101668460)

Registrant - Trifecta Pharmaceuticals USA LLC (079424163)

Revised: 5/2023

Pharmacy Value Alliance LLC