

**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.*

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**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**

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

## **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

## OUTER BOX



<b>DRUG FACTS</b>	<b>DRUG FACTS (continued)</b>
<b>Active ingredient</b> Hydrocortisone 1% <b>Anthi-Itch</b>	<b>Purpose</b> Anti-Itch
<b>Uses</b> 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	<b>Stop using this product and ask a doctor if:</b> ■ 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.
<b>Warnings</b> <b>For external use only</b> 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.	<b>Keep out of the reach of children.</b> If swallowed, get medical help or contact a Poison Control Center immediately.
<b>When using this product</b> ■ do not begin the use of any other hydrocortisone product unless you have consulted a doctor. ■ avoid contact with the eyes.	<b>Directions</b> 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.
<b>Other information</b> store at controlled room temperature 20°-25°C (68°-77°F).	<b>Other information</b> ■ do not begin the use of any other hydrocortisone product unless you have consulted a doctor. ■ avoid contact with the eyes.
<b>Inactive ingredients</b> Cetyl alcohol, Edetate disodium, Glyceryl monostearate, Methyparaben, Mineral oil, Polyorbate 60, Propylene glycol.	

## INNER TUBE



**Hydrocortisone Cream 1%**  
**ANTIPRURITIC (ANTI-ITCH)**

Maximum Strength  
Effective Itch & Rash Relief For Eczema, Insect Bites, Seborrheic Dermatitis, Psoriasis

NET WT. 1 OZ (28g)

**Active ingredient**  
Hydrocortisone 1%

**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 loading, stop use, consult a doctor. ■ do not put this product into the rectum by using fingers or any mechanical device or applicator.

**Purpose**  
Anti-Itch

**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.

**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:** Cetyl alcohol, Edetate disodium, Glyceryl monostearate, Methyparaben, Mineral oil, Polyorbate 60, Propylene glycol, Propylparaben, Purified water, Petroleum, Sulfonamide derivatives.

**Questions?** Call 1-866-633-4814

Distributed By: Pharmacy Value Alliance, LLC | 407 East Lancaster Avenue, Wayne, PA 19087 | Product of PRC

## HYDROCORTISONE

hydrocortisone 1% cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68016-149
<b>Route of Administration</b>	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
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>SORBITAN MONOSTEARATE</b> (UNII: NVZ4I0H58X)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68016-149-01	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