

**HYDROCORTISONE 1% WITH HEALING ALOE- hydrocortisone cream**  
**Trifecta Pharmaceuticals Usa Llc**

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**Hydrocortisone Cream 1% ANTIPRURITIC (Anti-Itch) with healing aloe**

**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***

temporary relieves 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 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**
- **avoid contact with the eyes**
- **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**
- in case of bleeding
- if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- before you begin using any other hydrocortisone product

**Do not use this product and ask a doctor**

● if you have a vaginal discharge ● before treating diaper rash ● before using on children under 2 years of age

**For External Anal Itching Users:** ● do not exceed the recommended daily dosage unless directed by a doctor

● in case of bleeding, consult a doctor promptly

● do not put this product into the rectum by using fingers or any mechanical device or applicator

● children under 12 years of age: consult a doctor

Before using any medication, read all label directions. Keep this carton. It contains important information.

### ***Directions***

●when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.

●gently dry by patting or blotting with toilet tissue or a soft cloth before applying.

●adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily.

●children under 12 years of age: do not use, consult a doctor.

### ***Inactive ingredients***

Aloe barbadensis leaf juice, ethylparaben, glycerin, glycerol monostearate, hexadecanol, mineral water, octadecanol, petrolatum, purified water, sodium dodecyl sulfate

### ***Other information***

● to open: unscrew cap and pull tab to remove foil seal

● if seal has been broken, do not use this product. Return product to the Store where you bought it

● store at controlled room temperature 15°-30°C ( 59 °- 86 °F)

see carton or tube crimp for lot number and expiration date

Distributed by:

**Trifecta Pharmaceuticals USA™**

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL 33301 USA

Product of PRC

**[www.trifecta-pharma.com](http://www.trifecta-pharma.com)**

# Packaging



COMPARE TO CORTIZONE • 10%  
ACTIVE INGREDIENT\*

NDC: 69396-005-20

with healing aloe

**Effective Itch & Rash Relief For  
Eczema, Psoriasis, Seborrheic Dermatitis**

**MAXIMUM STRENGTH**

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

**Hydrocortisone Cream 1%**  
**ANTIPRURITIC (Anti-Itch)**

\*Compare to Cortizone 10 Active Ingredient

Net Wt. 1 oz. (28.4g)

**MAXIMUM STRENGTH**

**Hydrocortisone Cream 1%**  
**ANTIPRURITIC (Anti-Itch)**  
**FAST RELIEF**

**100% GUARANTEED**

DRUG FACTS

Active ingredient	Purpose
Hydrocortisone 1%	Anti-Itch

**Uses**  
temporary relieves 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 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 • avoid contact with the eyes  
• 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 • in case of bleeding  
• if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days  
• before you begin using any other hydrocortisone product  
Do not use this product and ask a doctor  
• if you have a vaginal discharge • before treating diaper rash • before using on children under 2 years of age  
For External Anal Itching Users: • do not exceed the recommended daily dosage unless directed by a doctor  
• in case of bleeding, consult a doctor promptly  
• do not put this product into the rectum by using fingers or any mechanical device or applicator  
• children under 12 years of age: consult a doctor  
Keep out of the reach of children.  
If swallowed, get medical help or contact a Poison Control Center immediately.  
Before using any medication, read all label directions. Keep this carton. It contains important information.

**Directions**  
when practical, cleanse the affected area with mild soap and warm water and rinse thoroughly.  
• gently dry by patting or blotting with toilet tissue or a soft cloth before applying.  
• adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily.  
• children under 12 years of age: do not use, consult a doctor.

This product is manufactured or distributed by Challeng, Inc, distributor of Cortizone-10®

**Drug Facts (continued)**

**Other information**  
• to open: unscrew cap and pull tab to remove foil seal  
• if seal has been broken, do not use this product. Return product to the Store where you bought it  
• store at controlled room temperature 15°-30°C (59° - 86 °F)  
see carton or tube crimp for lot number and expiration date

**Inactive ingredients** Aloe barbadensis leaf juice, ethylparaben, glycerin, glycerol monostearate, hexadecanol, mineral water, octadecanol, petrolatum, purified water, sodium dodecyl sulfate

Distributed by:  
**Trifecta Pharmaceuticals USA™**  
101 NE Third Avenue, Suite 1500  
Ft Lauderdale, FL 33301 USA  
Product of P.R.C.  
[www.trifecta-pharma.com](http://www.trifecta-pharma.com)

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## HYDROCORTISONE 1% WITH HEALING ALOE

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69396-005
<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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-005-20	1 in 1 BOX	12/23/2015	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-005-05	1 in 1 BOX	08/23/2016	
2		15 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 Drug	M017	12/23/2015	

**Labeler** - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 12/2024

Trifecta Pharmaceuticals Usa Llc