

HYDROCORTISONE 1%- hydrocortisone cream
Trifecta Pharmaceuticals Usa Llc

Hydrocortisone Cream 1% ANTIPRURITIC (Anti-Itch)

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

For temporary relief of 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 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 a diaper rash, consult with doctor

For external genital itching if you have a vaginal discharge, consult 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 and consult a doctor.
- do not put this product into the rectum by using fingers or any medicated 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 of age and older: apply to the 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.

Inactive ingredients

Ethylparaben, glycerin, glyceryll monostearate, mineral oil, stearyl alcohol, petrolatum, purified water, sodium lauryl sulfate

Other information

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

Distributed by:

Trifecta Pharmaceuticals USA™

101 NE Third Avenue, Suite 1500

Ft. Lauderdale, FL 33301 USA

Product of PRC

www.trifecta-pharma.com

This product is not manufactured or distributed by Chattem Inc. distributor

Packaging



Globe®

**COMPARE TO CORTIZONE•10®
ACTIVE INGREDIENT***

NDC: 69396-055-01

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

MAXIMUM STRENGTH

Effective Relief Of Itches & Rashes Due To:

- Eczema • Seborrheic Dermatitis • Psoriasis • Insect Bites
- Poison Ivy, Oak, and Sumac • External Feminine, 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. (28g)

MAXIMUM STRENGTH



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This product is not manufactured or distributed by Challengin, Inc., distributor of Cortizone 10®.

<p>Drug Facts (continued)</p> <p>Other Information</p> <p>store at controlled room temperature 20° - 25° C (68° - 77° F).</p>	<p>Inactive Ingredients</p> <p>Petrolatum, Purified water, Sodium lauryl sulfate, Stearyl alcohol, Glycerin, Glyceryl monostearate, Mineral oil.</p>
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Directions

Keep out of the reach of children. If swallowed, get medical help or contact a Poison Control Center immediately.

product unless directed by a doctor.

occurs 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.

Stop using this product and ask a doctor if:

- symptoms persist for more than 7 days or clear up and
- symptoms worsen
- conditions worsen

adults and children 2 years and older

Children under 2 years of age

- do not use.
- 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.

Distributed by:

Thelma Pharmaceuticals USA®

101 Third Avenue, Suite 1500
Ft. Lauderdale, FL 33301 USA
Product of PFC
www.thelma-pharma.com

<p>Drug Facts</p> <p>Active ingredient</p> <p>Hydrocortisone 1% (Anti-Itch)</p> <p>Purpose</p> <p>For temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:</p> <ul style="list-style-type: none"> • eczema • insect bites • poison ivy • poison oak • allergic dermatitis • psoriasis • contact dermatitis • seborrheic dermatitis • scabies • external genital and anal itching <p>Other uses of this product should be only under the advice and supervision of a doctor.</p>	<p>Warnings</p> <p>For external use only</p> <ul style="list-style-type: none"> • 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. <p>When using this product</p> <ul style="list-style-type: none"> • 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 put this product into the rectum by using fingers or any mechanical device or applicator. • By a doctor: In cases of bleeding, stop use, consult a doctor.
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FAST RELIEF
ANTIPRURITIC (Anti-Itch)
Hydrocortisone Cream 1%

100% GUARANTEED



NDC: 69396-055-01

Hydrocortisone

Cream 1%

ANTIPRURITIC (Anti-Itch)

Net Wt. 1 oz. (28g)

MAXIMUM STRENGTH

Active Ingredient

Hydrocortisone 1%

Use: For temporary relief of itching associated with minor skin irritations, inflammation and redness due to:
• insect bites • poison ivy • poison oak • poison sumac • soaps • detergents • cosmetics • jewelry • rubber/latex 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.

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 pulling 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: Ethylparaben, Glycerin, Glyceryl monostearate, Mineral oil, Stearyl Alcohol, Petrolatum, Purified water, Sodium lauryl sulfate.
Questions? Call 1-888-286-8997.

Distributed by: Trilecta Pharmaceuticals USA®
101 NE Third Avenue, Suite 1500, Ft. Lauderdale, FL 33301 USA | Product of PRC | www.trilecta-pharma.com

HYDROCORTISONE 1%

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-055
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
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-055-01	1 in 1 BOX	02/21/2019	

1	28 g in 1 TUBE; Type O: Not a Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	02/20/2019	

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 12/2024

Trifecta Pharmaceuticals Usa Llc