

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, glycerol monostearate, hexadecanol, mineral water, octadecanol, petrolatum, purified water, sodium dodecyl sulfate

Other information

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

Distributed by:

Trifecta Pharmaceuticals USA™

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Ft. Lauderdale, FL 33301 USA

Product of PRC

www.trifecta-pharma.com



HYDROCORTISONE 1%

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69396-050
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BP) (HYDROCORTISONE - UNII:W4X0X7BP)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONO AND DIPALMITOSTEARATE (UNII: KC98RO82HJ)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69396-050-01	1 in 1 BOX	12/12/2019	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:69396-050-05	1 in 1 BOX	09/01/2022	
2		14.2 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	12/12/2019	

Labeler - Trifecta Pharmaceuticals Usa Llc (079424163)

Revised: 3/2026

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