

HYDROCORTISONE 1%- hydrocortisone cream
Chain Drug Marketing Association Inc.

Quality Choice Hydrocortisone Cream 1%

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

Cetyl alcohol, Edetate disodium, Methylparaben, Mineral Oil, Mono-and-di-glycerides, Polysorbate 60, Propylene glycol, Propylparaben, Purified Water, Petrolatum, Sorbitan monostearate

Other information

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

Distributed by: CDMA, Inc.

Novi, MI. 48375

www.qualitychoice.com

Questions: 800-935-2362

This product is not manufactured or distributed by Valeant Pharmaceuticals North America, Inc. distributor of Cortaid.

• 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 products unless you have consulted a doctor.
 • do not use on 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.

Hydrocortisone, Methyl 66, Benzoin 2, 2-pyridone, Petrolatum, Polysorbate 60, Propylene glycol, Propylparaben, Purified water, Sorbitan monostearate.

This product is not manufactured or distributed by Fresenius Pharmaceutics Health America, the distributor of Cortace.

Distributed by: CDMA, Inc.
 New, HI 48374
 www.qualitychoice.com
 Questions: 800-955-2362



HYDROCORTISONE 1%

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-047
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
PETROLATUM (UNII: 4T6H12BN9U)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX25C1OH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
GLYCERYL MONO- AND DICAPRYLATE (UNII: 34966F76M6)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
MINERAL OIL (UNII: T5L8T28FGP)	

Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:83324-047-01	1 in 1 BOX	03/15/2024	
1		28.3 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	03/15/2024	

Labeler - Chain Drug Marketing Association Inc. (011920774)

Registrant - Trifecta Pharmaceuticals USA LLC. (079424163)

Revised: 6/2024

Chain Drug Marketing Association Inc.