

HYDROCORTISONE 1%- hydrocortisone cream
Geri-Care Pharmaceuticals, Corp

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.

Geri-Care Hydrocortisone Cream 1%

MAXIMUM STRENGTH

DRUG FACTS

Active ingredient

Hydrocortisone 1%

Purpose

Antipruritic (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 and rashes

- external feminine, genital and anal itching

Other uses of this product should be only under the advice and supervision of a doctor

Do Not Use

- For the treatment of diaper rash, consult a doctor.
- With any other Hydrocortisone product unless you have consulted a doctor
- If you have a vaginal discharge, consult a doctor

Warnings

For external use only

When using this product

- Avoid Contact with the eyes
- do not exceed the recommended daily dosage unless directed by 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 worsens, symptoms persist for more than 7 days or symptoms clear up and reappear 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.
- Rectal bleeding occurs

Directions

For Itching or skin irritation, inflammation, and rashes:

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 and ask a doctor.

For External and anal itching in adults:

When practical, clean 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
apply to affected area not more than 3 to 4 times daily.

For children under 12 years of age: Ask a doctor

Inactive ingredients

Cetareth-20, Cetearyl alcohol, Ethylhexylglycerin, Glycerin, Glyceryl Stearate, mineral oil, petrolatum, Phenoxyethanol, water.

Other information

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

Tamper evident, do not use if packet is torn, cut or opened.

Avoid excessive heat and humidity.

Questions

Call 1-800-540-3765

Distributed By

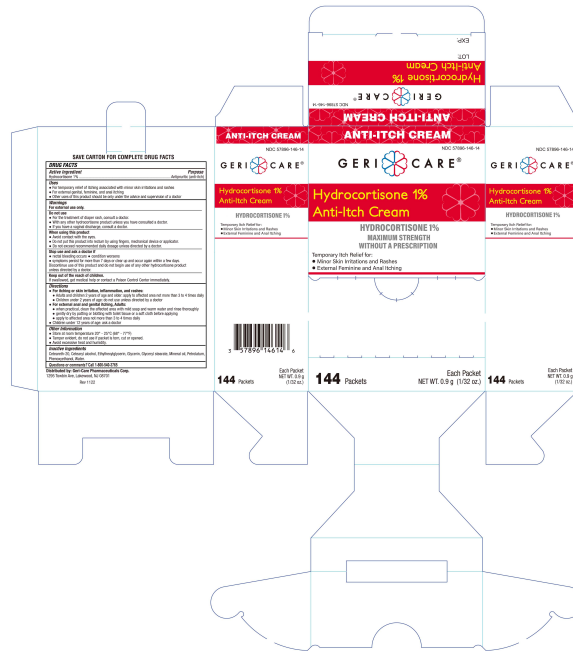
Distributed By

Geri-Care Pharmaceuticals Corp

1295 Towbin Ave.

Lakewood, NJ 08701

OUTSIDE BOX



INNER PACKET



HYDROCORTISONE 1%

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57896-146
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
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
MINERAL OIL (UNII: T5L8T28FGP)	
GLYCERIN (UNII: PDC6A3COOX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

PETROLATUM (UNII: 4T6H12BN9U)	
WATER (UNII: 059QF0KO0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57896-146-14	144 in 1 CARTON	05/31/2023	
1		0.9 g in 1 PACKET; 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	05/31/2023	

Labeler - Geri-Care Pharmaceuticals, Corp (611196254)

Registrant - Trifecta Pharmaceuticals USA (079424163)

Revised: 6/2023

Geri-Care Pharmaceuticals, Corp