

CARING MILLS HYDROCORTISONE- hydrocortisone cream
Veridian Healthcare

Caring Mills Hydrocortisone Cream 2 oz

Active Ingredient:

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves itching associated with minor skin irritations, inflammation, and rashes due to:
 - eczema
 - psoriasis
 - poison ivy, oak, sumac
 - insect bites
 - detergents
 - jewelry
 - cosmetics
 - soaps
 - seborrheic dermatitis
- temporarily relieves external anal and genital itching
- other uses of this product should only be under the advice and supervision of a doctor

Warnings

For external use only

Do not use

- in the genital area if you have a vaginal discharge.
- for the treatment of diaper rash.
- with any other hydrocortisone product unless you have asked a doctor

When using this product

- use only as directed
- avoid contact with eyes
- do not use more than directed unless told to do so by a doctor
- do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

- condition worsens, symptoms persist for more than 7 days or clear up and occur again within a few days, and do not begin use of any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away. (1-800-222-1222)

Directions

- **for itching of skin irritation, inflammation, and rashes:**
- adults and children 2 years of age and over: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: consult a physician
- **for external anal and genital itching, adults and children 12 years of age and over:**
 - when practical, clean 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
 - apply to affected area not more than 3 to 4 times daily
 - children under 12 years of age: consult a physician

Other information

Store at 20-25C (68-77F)

do not use if tube seal under cap is broken

Inactive Ingredients

cetostearyl alcohol, edetate sodium, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, sorbitan monostearate water.

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CARING MILLS HYDROCORTISONE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71101-800
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
EDETATE SODIUM (UNII: MP1J8420LU)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71101-800-01	1 in 1 CARTON	05/01/2023	
1		56.6 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	05/01/2023	

Labeler - Veridian Healthcare (830437997)

Establishment

Name	Address	ID/FEI	Business Operations
Anicare Pharmaceuticals Private Limited		916837425	manufacture(71101-800)

Revised: 12/2024

Veridian Healthcare