

CARING MILLS HYDROCORTISONE- hydrocortisone cream
Veridian Healthcare

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.

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.

Caring Mills Hydrocortisone Cream 2 oz



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 not final	part348	05/01/2023	

Labeler - Veridian Healthcare (830437997)

Establishment

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

Revised: 5/2023

Veridian Healthcare