

CAREONE ANTI ITCH- hydrocortisone cream

Velocity Pharma LLC

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.

Anti-Itch Cream

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

- for the treatment of diaper rash. Ask a doctor.
- in the genital area if you have a vaginal discharge. Ask a doctor.

When using this product

- avoid contact with the 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.

Directions

- for itching of skin irritation, inflammation, and rashes:
- adults and children 2 years of age and older: apply to affected area not more than 3 to 4 times daily
- children under 2 years of age: do not use, ask a doctor
- for external anal and genital itching, adults:
- 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: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)


Inactive ingredients

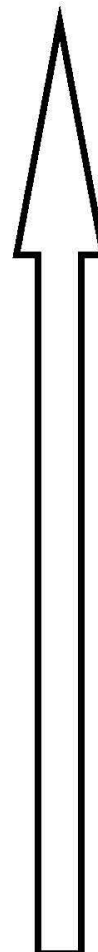
aloe barbadensis leaf juice, avena sativa (oat) kernel extract, benzyl alcohol, butylated hydroxytoluene, cetostearyl alcohol, cetyl alcohol, chamomilla recutita (matricaria) flower extract, diazolidinyl urea, dimethicone, distearyldimonium chloride, edetate disodium, glycerin, glyceryl monostearate, hydrolyzed collagen, hydrolyzed elastin, hydrolyzed jojoba esters, jojoba esters, magnesium ascorbyl phosphate, menthyl lactate, methyl gluceth-20, methylparaben, petrolatum, polysorbate 60, potassium hydroxide, PPG-12/SMDI copolymer, propylparaben, purified water, retinyl palmitate, stearamidopropyl PG-dimonium chloride phosphate, steareth-2, steareth-21, stearyl alcohol, tocopheryl acetate

Questions or comments?

Keep Carton for complete information i.e. Help line number and company address

Principal Display Panel

CareOne Anti-Itch Cream 2 Oz			
Active Ingredient			
Hydrocortisone		Anti-Itch	
BATCH NO.		QUANTITY	x 56.7 g = Tubes
MFG. DATE	05/2018	SHIPPER NO.	--- out of ---
EXP. DATE	04/2020	GROSS WT.	----- kg.
		NET WT.	----- kg.
WARNING: KEEP OUT OF REACH OF CHILDREN AND PETS. FOR EXTERNAL USE ONLY.		STORE AT CONTROLLED TEMPERATURE OF 59°F to 86° F (15 to 30 °C)	
CONFORMANCE WITH THE F.D & C ACT AND REGULATIONS THERE UNDER		PROTECT FROM DIRECT SUNLIGHT / MOISTURE / FREEZING	
MANUFACTURED BY: SOTAC PHARMACEUTICALS PVT LTD PLOT NO. PF-21, SANAND GIDC-II, CHARAL INDUSTRIAL ESTATE, TALUKA-SANAND, DISTRICT-AHMEDABAD 382 110. INDIA			
Lic# GUJ/DRUGS/G/25/2169		Labeler Code: 72351	
SHIPPED TO: VELOCITY PHARMA LLC 226/B SHERWOOD AVE, FARMINGDALE , NY-11735			
NDC No	72351-006-00		
Barcode No.			
	3	41520	00437 7



CAREONE ANTI ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72351-006
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0 X7BPJ) (HYDROCORTISONE - UNII:W14X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z8 3H0 X)	

OAT (UNII: Z6J799EAJK)
BENZYL ALCOHOL (UNII: LKG8494WBH)
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CETYL ALCOHOL (UNII: 936JST6JCN)
CHAMOMILE (UNII: FGL3685T2X)
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)
DIMETHICONE (UNII: 92RU3N3Y1O)
DISTEARYLDIMONIUM CHLORIDE (UNII: OM9573ZX3X)
EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)
HYDROLYZED JOJOBA ESTERS (ACID FORM) (UNII: UDR641JW8W)
MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5)
MENTHYL LACTATE, (-) (UNII: 2BF9E65L7I)
METHYL GLUCETH-20 (UNII: J3QD0LD11P)
METHYL PARABEN (UNII: A218C7H9T)
PETROLATUM (UNII: 4T6H12BN9U)
POLYSORBATE 60 (UNII: CAL22UVI4M)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0KO0R)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
STEARETH-2 (UNII: V56DFE46J5)
STEARETH-21 (UNII: 53J3F32P58)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)

Product Characteristics

Color	white (Off white)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72351-006-00	81 in 1 BOX	06/11/2018	
1		56.7 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	06/11/2018	

Labeler - Velocity Pharma LLC (876894019)

