

## **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.*

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### **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

hydrocortisone cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76 168-207
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0 X7BPJ) (HYDROCORTISONE - UNII:WI4X0 X7BPJ)	HYDROCORTISONE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY8 1Z83H0 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: A2I8C7HI9T)
PETROLATUM (UNII: 4T6H12BN9U)
POLYSORBATE 60 (UNII: CAL22UVI4M)
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
WATER (UNII: 059QF0K00R)
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)
STEARETH-2 (UNII: V56DFE46J5)
STEARETH-21 (UNII: 53J3F32P58)
STEARYL ALCOHOL (UNII: 2KR89I4HIY)

### 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:76168-207-30	1 in 1 CARTON	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 (962198409)