

**CAREONE ANTI ITCH- hydrocortisone cream**  
**American Sales Company**

*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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**American Sales Company Anti-Itch Cream Drug Facts**

**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 be only 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. Ask a doctor.
- for the treatment of diaper rash. 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, aluminum sulfate, calcium acetate, cetearyl alcohol, cetyl alcohol, cholecalciferol, dextrin, glycerin, isopropyl palmitate, light mineral oil, maltodextrin, methylparaben, propylene glycol, propylparaben, purified water, retinyl palmitate, sodium cetearyl sulfate, sodium lauryl sulfate, tocopherol, white petrolatum, white wax, zea mays (corn) oil

**Questions or comments?**

1-800-719-9260

**Principal Display Panel**

Compare to the active ingredient in Cortizone – 10® Plus

Maximum Strength

Anti-Itch Cream

Plus 10 Moisturizers

Anti-Itch Cream

Relieves Itch Fast

Hydrocortisone 1%

OUR PHARMACISTS RECOMMEND

NET WT 1 OZ (28g)

NDC 41520-033-64

CAREone®

Compare to the active ingredient in Cortizone•10® Plus\*

Maximum Strength Anti-Itch Cream Plus 10 Moisturizers

CAREone®

Maximum Strength Anti-Itch Cream

Anti-Itch Cream Relieves Itch Fast

Hydrocortisone 1%



NET WT 1 OZ (28g)



Drug Facts

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 be only 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. Ask a doctor. for the treatment of diaper rash. 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 rectal bleeding occurs 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

Drug Facts (continued)

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Other information

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Inactive ingredients

aloe barbadensis leaf juice, aluminum sulfate, calcium acetate, cetearyl alcohol, cetyl alcohol, cholecalciferol, dextrin, glycerin, isopropyl palmitate, light mineral oil, malodextrin, methylparaben, propylene glycol, propylparaben, purified water, retinyl palmitate, sodium cetearyl sulfate, sodium lauryl sulfate, tocopherol, white petrolatum, white wax, zea mays (corn) oil

Questions or comments? 1-800-719-9260

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\*This product is not manufactured or distributed by Chatham, Inc., distributor of Cortizone•10® Plus.

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Quality guaranteed or your money back.



CAREONE ANTI ITCH

hydrocortisone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41520-033
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ALUMINUM SULFATE (UNII: 34S289N54E)	
CALCIUM ACETATE (UNII: Y882YXF34X)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CHOLECALCIFEROL (UNII: 1C6V77QF41)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
VITAMIN A PALMITATE (UNII: 1D1K0N0VVC)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PETROLATUM (UNII: 4T6H12BN9U)	
WHITE WAX (UNII: 7G1J5DA97F)	
CORN OIL (UNII: 8470G57WFM)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-033-64	1 in 1 CARTON	05/19/2016	
1		28 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	05/19/2016	

**Labeler** - American Sales Company (809183973)

Revised: 9/2017

American Sales Company