

CARE ONE HYDROCORTISONE MAXIMUM STRENGTH- 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.

American Sales Company Maximum Strength Hydrocortisone 1% 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 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. Consult a doctor.
- for the treatment of diaper rash. Consult 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 (1-800-222-1222).

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, consult 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: consult a doctor

Other information

- store at 20-25°C (68-77°F)

Inactive ingredients

water, cetearyl alcohol, cetareth-20, cetyl palmitate, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, aloe barbadensis leaf juice

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to the active ingredient in Cortizone•10® Creme

Plus a Soothing Moisturizer

Maximum Strength

Hydrocortisone 1% Cream

Anti-Itch Cream/With Soothing Aloe

Relieves Itch Fast

Hydrocortisone 1%

OUR PHARMACISTS RECOMMEND

NET WT 1 OZ (28g)

NDC 41520-319-64

CAREone®

Compare to the active ingredient in Cortizone•10® Creme*

Plus a Soothing Moisturizer Maximum Strength Hydrocortisone 1% Cream

CAREone®

Maximum Strength Hydrocortisone 1% Cream

Anti-Itch Cream/With Soothing Aloe
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CODE AREA



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Drug Facts (continued)

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*This product is not manufactured or distributed by Chattem, Inc., distributor of Cortizone•10® Creme.

CODE AREA



CARE ONE HYDROCORTISONE MAXIMUM STRENGTH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-319
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128MIS)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0K00R)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-319-64	1 in 1 CARTON	05/12/2017	
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	05/28/2010	

Labeler - American Sales Company (809183973)

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American Sales Company