

ANTI-ITCH- hydrocortisone 1% spray

Car One

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.

Car One Labs Drug Facts

Active ingredient

Hydrocortisone - 1.00%

Purpose

Anti-itch

Uses

For the temporary relief of itching associated with minor skin irritation and rashes due to: • eczema • poison ivy, oak and sumac • cosmetics • jewelry • soaps and detergents • insect bites. Other uses of this product should be only under the advice and supervision of a doctor.

Warnings

For external use only.

Flammable: Keep away from fire or flame

Avoid contact with the eyes. If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a doctor.

Do not use for the treatment of diaper rash. Consult a doctor.

Do not puncture or incinerate. Contents under pressure. Do not store at temperatures above 120°F

Keep out of reach of the children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- 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

Inactive ingredients

Citric Acid, Disodium EDTA, Glycerin, Poloxamer 188, Polysorbate 20, SD Alcohol 40-B, Water

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Compare to the active ingredient in Cortizone-10® Quick Shot™*

CAREONE™
1% HYDROCORTISONE
ANTI-ITCH
SPRAY

SPRAYS AT ANY ANGLE

- Touchless Application
- Temporarily Relieves Itching Associated with Insect Bites, Poison Ivy, Sunburn, Rashes, & Irritation

3 FL OZ
(88 mL)

Drug Facts

Active ingredient	Purpose
Hydrocortisone 1%	Anti-Itch

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Questions? 1-877-846-9949

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ANTI-ITCH

hydrocortisone 1% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-366
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

Glycerin (UNII: PDC6A3C0OX)	
Poloxamer 188 (UNII: LQA7B6G8JG)	
Polysorbate 20 (UNII: 7T1F30V5YH)	
ALCOHOL (UNII: 3K9958V90M)	
Water (UNII: 059QF0K00R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-366-03	85 g in 1 CAN; Type 0: Not a Combination Product	02/19/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	02/19/2013	

Labeler - Car One (809183973)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(41520-366) , label(41520-366)

Revised: 6/2018

Car One