

MAXIMUM STRENGTH ANTI-ITCH- hydrocortisone 1% spray

Quality Choice

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.

Drug Facts

Active ingredient

Hydrocortisone - 1.00%

Purpose

Anti-itch

Uses

Temporarily relieves itching associated with minor skin irritation and rashes due to:

- eczema
- psoriasis
- insect bites
- poison ivy, oak and sumac
- soaps and detergents
- seborrheic dermatitis
- cosmetics
- jewelry

Warnings

For external use only

Flammable: Do not use while smoking or near heat or flame

When using this product

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.F

Ask doctor before use if you are using any other hydrocortisone product

Keep out of reach of the children

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

Directions

- shake well
- 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: ask a doctor
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

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



Compare to the active ingredient in CORTAID

Maximum Strength Anti-Itch Spray

Itch Relief

Hydrocortisone 1% | Anti-Itch

Temporarily Relieves Itching From:

- Skin Irritation
- Rashes
- Insect Bites
- Eczema
- Psoriasis

Continuous Spray at Any Angle



Drug Facts

Active ingredient	Purpose
Hydrocortisone 1%.....	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 children. If swallowed, get medical help or contact a Poison Control Center immediately.

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.

Questions? 248-449-9300

This product is not manufactured or distributed by Valeant Consumer Products, distributor of Cortaid.



Distributed by C.D.M.A., Inc.®
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MAXIMUM STRENGTH ANTI-ITCH

hydrocortisone 1% spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63868-782
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:63868-782-03	85 g in 1 CAN; Type 0: Not a Combination Product	04/07/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/07/2014	

Labeler - Quality Choice (011920774)

Registrant - Product Quest Mfg (927768135)

Establishment

Name	Address	ID/FEI	Business Operations
Product Quest Mfg		927768135	manufacture(63868-782) , label(63868-782)

Revised: 6/2018

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