HYDROCORTISONE- hydrocortisone continuous spray aerosol, spray Premier Brands of America, Inc.

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.

Cutter Poison Ivy Itch Relief

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:

- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- jewelry
- detergents
- cosmetics
- seborrheic dermatitis
- psoriasis
- 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 heat, sparks and open flame. Contents under pressure. Do not puncture or incinerate. Do not store at temperatures above 120 °F. Intentional misuse by deliberately concentrating and inhaling contents can be harmful or fatal.

Do not use

• for external genital, vaginal or anal itching

- with other hydrocortisone product unless directed by a doctor
- in or near the eyes
- for diaper rash

When using this product

- avoid contact with the eyes
- if product gets into the eye, flush with water for 15 minutes

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 consulted a doctor

Keep out of the reach of children.

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

Directions

- twist cap counterclockwise to unlock actuator
- adults and children 2 years of age and older: spray affected area not more than 3 to 4 times daily
- children under 2 years of age: do not use, consult a doctor
- to apply to face, spray into palm of hand and gently apply

Inactive ingredients

aloe barbadensis leaf juice, avena sativa (oat) kernel extract, citric acid, disodium EDTA, ethoxydiglycol, glycerin, maltodextrin, menthyl lactate, methyl gluceth-20, PEG-8, SD alcohol 40-B, sodium citrate, water

Questions?

Call 1-866-964-0939

Principal Display Panel

Cutter

Poison Ivy Itch Relief

For Poison Ivy, Oak, & Sumac

Maximum Strength

Relieves Itching

Calms irritated skin

No touch, no mess

HYDROCORTISONE 1% / ANTI-ITCH



HYDROCORTISONE

hydrocortisone continuous spray aerosol, spray

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56104-250
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) HYDROCORTISONE 1.13 g in 113 g

Inactive Ingredients			
Ingredient Name	Strength		
EDETATE DISODIUM (UNII: 7FLD91C86K)			
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)			
GLYCERIN (UNII: PDC6A3C0OX)			
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)			
SODIUM CITRATE (UNII: 1Q73Q2JULR)			
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	
OAT (UNII: Z6J799EAJK)	
WATER (UNII: 059QF0KO0R)	
DIETHYLENE GLYCOL MONOETHYL ETHER (UNII: A1A1I8X02B)	
ALCOHOL (UNII: 3K9958V90M)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	

Packaging					
# Item Co	de Package Description	Marketing Start Date	Marketing End Date		
1 NDC:56104-2	250- 113 g in 1 CAN; Type 0: Not a Combinat Product	ion 12/20/2021			

Marketing Information					
Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
part348	12/20/2021				
	Application Number or Monograph Citation	Application Number or Monograph Marketing Start Citation Date			

Labeler - Premier Brands of America, Inc. (117557458)

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