AVEENO HYDROCORTISONE ANTI-ITCH- hydrocortisone cream Johnson & Johnson Consumer 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.

Aveeno 1% Hydrocortisone ANTI-ITCH Cream

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-Itch

Use

For the temporary relief of itching associated with minor skin irritations and rashes due to:

- eczema
- insect bites
- poison ivy, oak or sumac
- soaps and detergents
- cosmetics
- iewelry
- seborrheic dermatitis
- psoriasis
- Other uses of this product should be only under the advice and supervision of doctor

Warnings

For external use only.

Do not use

- in or near the eyes
- for diaper rash; ask a doctor

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

Stop use and ask a doctor if

- condition worsens or if symptoms persists for more than 7 days
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of 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; ask a doctor.

Sunburn Alert

This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

Other information

Protect from Excessive Heat (40°c/104°F)

Inactive ingredients

Water, Cetearyl Alcohol, Glycerin, Isopropyl Myristate, Cetereath-20, Cyclopentasiloxane, Avena Sativa (Oat) Kernel flour, Cetyl Palmitate, Isostearyl Neopentanoate, Benzyl Alcohol, Dimethicone/Vinyltrimethylsiloxysilicate Crosspolymer, Potassium Lactate, PEG-40 Stearate, Methylparaben, Citric Acid, Tocopheryl Acetate, Aloe Barbadensis Leaf Extract, Avena Sativa (Oat) Kernel Oil, Avena Sativa (Oat) Kernel Extract, Sodium Hydroxide

Questions?

866-428-3366; Outside US, dial collect 215-273-8755 www.aveeno.com

Distributed by:

JOHNSON & JOHNSON CONSUMER INC.

Skillman, NJ 08558

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Aveeno®

1% Hydrocortisone

ANTI-ITCH CREAM

Effectively relieves itch from:

Eczema Psoriasis

Poison Ivy ● Oak ● Sumac

Insect Bites ● Detergents ● Soaps

Maximum Strength Formula

Specially formulated for longer-lasting relief

With Triple Oat, Aloe, & Vitamin E

DERMATOLOGIST RECOMMENDED BRAND

TRIPLE OAT

net wt. 1 oz (28 g)



AVEENO HYDROCORTISONE ANTI-ITCH hydrocortisone cream Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:69968-0511 Route of Administration TOPICAL Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
GLYCERIN (UNII: PDC6A3C0OX)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
OATMEAL (UNII: 8PI54V663Y)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
POTASSIUM LACTATE (UNII: 87V1KMK4QV)	
METHYLPARABEN (UNII: A218C7H19T)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
.ALPHATOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
OAT KERNEL OIL (UNII: 3UVP41R77R)	
OAT (UNII: Z6J799EAJK)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	

Packaging						
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:69968- 0511-1	1 in 1 CARTON	03/01/2019			
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	03/01/2019		

Labeler - Johnson & Johnson Consumer Inc. (118772437)