

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

Uses

Temporary relieves itching associated with minor skin irritations, inflammation and rashes due to:

- eczema
- soaps and detergents
- insect bites
- poison ivy, oak or sumac
- cosmetics
- seborrheic dermatitis
- psoriasis
- jewelry
- Other uses of this product: ask a 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 persist for 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 immediately.

Directions

- apply to affected area not more than 3 to 4 times daily.
- children under 2 years of age, do not use; ask a doctor.

Other information

Protect from excessive heat (40°C/100°F).

Inactive ingredients

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

Questions?

866-4AVEENO (or 866-428-3366) or 215-273-8755 (collect) www.aveeno.com

Distributed in the US by:

**JOHNSON & JOHNSON
CONSUMER PRODUCTS COMPANY**

Division of Johnson & Johnson
Consumer Companies, Inc.
Skillman, NJ 08558-9418

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Dermatologist Recommended

Aveeno®

ACTIVE NATURALS®

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 Complex, Aloe, & Vitamin E

NET WT. 1 OZ. (28g)

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0K00R)	
Cetostearyl Alcohol (UNII: 2DMT128M1S)	
Glycerin (UNII: PDC6A3C0OX)	
Polyoxyl 20 Cetostearyl Ether (UNII: YRC528SWUY)	
Isopropyl Myristate (UNII: 0RE8K4LNJS)	
Cyclomethicone 5 (UNII: 0THT5PC10R)	
Oatmeal (UNII: 8PI54V663Y)	
Benzyl Alcohol (UNII: LKG8494WBH)	
Cetyl Palmitate (UNII: 5ZA2S6B08X)	
Isostearyl Neopentanoate (UNII: 411THY156Q)	
Citric Acid Monohydrate (UNII: 2968PHW8QP)	
Potassium Lactate (UNII: 87V1KMK4QV)	
PEG-40 Stearate (UNII: ECU18C66Q7)	
Methylparaben (UNII: A218C7H9T)	
Oat Kernel Oil (UNII: 3UVP41R77R)	
.Alpha.-Tocopherol Acetate (UNII: 9E8X80D2L0)	
Aloe Vera Leaf (UNII: ZY81Z83H0X)	
Tanacetum Parthenium (UNII: 6GE7Z0761K)	
Oat (UNII: Z6J799EAJK)	
Sodium Hydroxide (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58232-1402-1	1 in 1 CARTON	10/08/2012	
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	10/08/2012	

Labeler - Johnson & Johnson Consumer Inc. (002347102)