

DERMACORT ANTI-ITCH- hydrocortisone cream
Melaleuca, 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.

Dermacort Anti-Itch Cream content of label

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, psoriasis, seborrheic dermatitis, poison ivy, poison oak, poison sumac, insect bites, soaps, detergents, and jewelry
- other uses of this product should be only under the advice and supervision of a doctor

Warnings

For external use only

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

When using this product avoid contact with the eyes

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 asked a doctor

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.

Other information do not store above 100°F (38°C)

Inactive ingredients acrylates/C10-30 alkyl acrylates crosspolymer, cetyl alcohol, cyclopentasiloxane, deionized water, dimethicone, glycerin USP, glyceryl stearate and PEG-100 stearate, isopropyl palmitate, Melaleuca Oil, methylparaben, petrolatum USP, propylparaben, steareth-2, steareth-21, triethanolamine

3/32" No Print Area

Drug Facts

Active ingredient Purpose
Hydrocortisone 1%.....Anti-itch

Uses ■ for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to eczema, psoriasis, seborrheic dermatitis, poison ivy, poison oak, poison sumac, insect bites, soaps, detergents, and jewelry ■ other uses of this product should be only under the advice and supervision of a doctor

Warnings
For external use only

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

When using this product avoid contact with the eyes

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 asked a doctor

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.

Other information do not store above 100°F (38°C)

Inactive ingredients acrylates/C10-30 alkyl acrylates crosspolymer, cetyl alcohol, cyclopentasiloxane, deionized water, dimethicone, glycerin USP, glyceryl stearate and PEG-100 stearate, isopropyl palmitate, Melaleuca Oil, methylparaben, petrolatum USP, propylparaben, steareth-2, steareth-21, triethanolamine

DERMACORT[®]

ANTI-ITCH CREAM

• 1% Hydrocortisone Cream • With T36-C5[®] Melaleuca Oil

NET WT 1 OZ (28 g)



Melaleuca, Inc.
Idaho Falls, ID 83402-6003
To order: 1-800-282-3000
www.melaleuca.com
Product of USA #3152 03/11U
NOT FOR RESALE IN CANADA

1/8" No Print Area

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:54473-117
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 1G56KV7BUJ)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE 5 (UNII: 0THF5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYOXYL 100 STEARATE (UNII: YD01N1999R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
STEARETH-2 (UNII: V56DFE46J5)	
STEARETH-21 (UNII: 53J3F32P58)	
TEA TREE OIL (UNII: VIF565UC2G)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-117-01	28 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	08/02/2000	

Labeler - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
-------------	----------------	---------------	----------------------------

