

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

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 use of this product should be only under the advice and supervision of a doctor.

Warnings

For external use only.

When using this product avoid contact with the eyes.

Stop use and ask a doctor if conditions 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.

Keep out of reach of children.

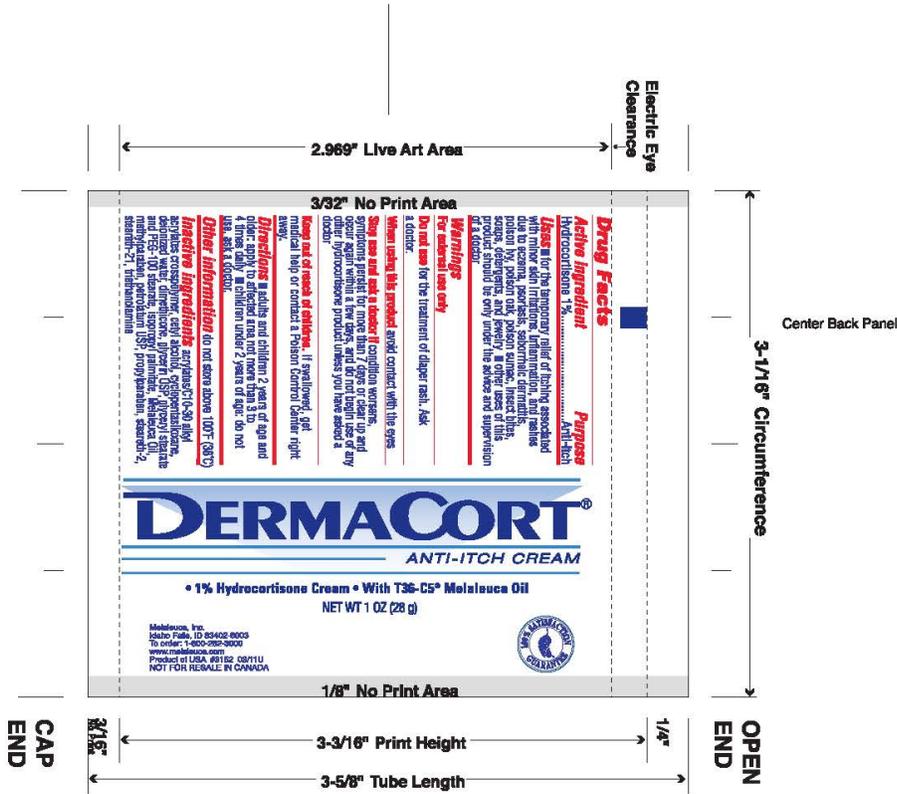
In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately.

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.

Other information Do not store above 100°F.

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, Serareth-2, Steareth-21, Triethanolamine.

Compax 1" x 3-5/8"



505003152

LEGEND	
	Pantone 279 C
	PANTONE 2746 C
	PANTONE 485 CVC

Customer _____

Date _____

NOTE: CHANGES ARE COSTLY AND WILL CAUSE ADDITIONAL EXPENSE AND DELAY

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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: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
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)	
CARBOMER COPOLYMER TYPE B (ALLYL PENTAERYTHRITOL CROSSLINKED) (UNII: 809Y72KV36)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54473-117-28	28 g in 1 TUBE; Type 0: Not a Combination Product	01/01/2018	

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)

Registrant - Melaleuca, Inc. (139760102)

Establishment

Name	Address	ID/FEI	Business Operations
Melaleuca, Inc.		079711683	manufacture(54473-117)

Revised: 5/2023

Melaleuca, Inc.