ALOE CORT- hydrocortisone cream
Topiderm, Inc.

Aloe Cort Cream

Drug Facts

Active ingredient

Hydrocortisone USP 1%

Purpose

Antipruritic cream

Uses

For the temporary relief of itching from minor skin irritations, and rashes
- Other uses of this product should be only under the supervision of a doctor.

Directions

Adults and children 2 years of age and older: Apply to affected area not more than 3 to 4 times daily, or as directed. Consult a physician for children under 2 years of age.

Warnings
- For external use only
- Avoid contact with the eyes. If condition 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 consult a physician
- Do not use for treatment of diaper rash
- Keep out of reach of children. If swallowed, seek professional assistance or contact a Poison Control Center immediately.

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Beeswax, Benzyl Alcohol, Carbomer, Cetearyl Alcohol, Dimethicone, Glycerin, Imidazolidinyl Urea, Methylparaben, PPG-2 Myristyl Ether Propionate, Polysorbate-60, Propylparaben, Purified Water, Squalane, Triethanolamine.

PRINCIPAL DISPLAY PANEL - 57 g Tube Label

DERMA
TOPIX

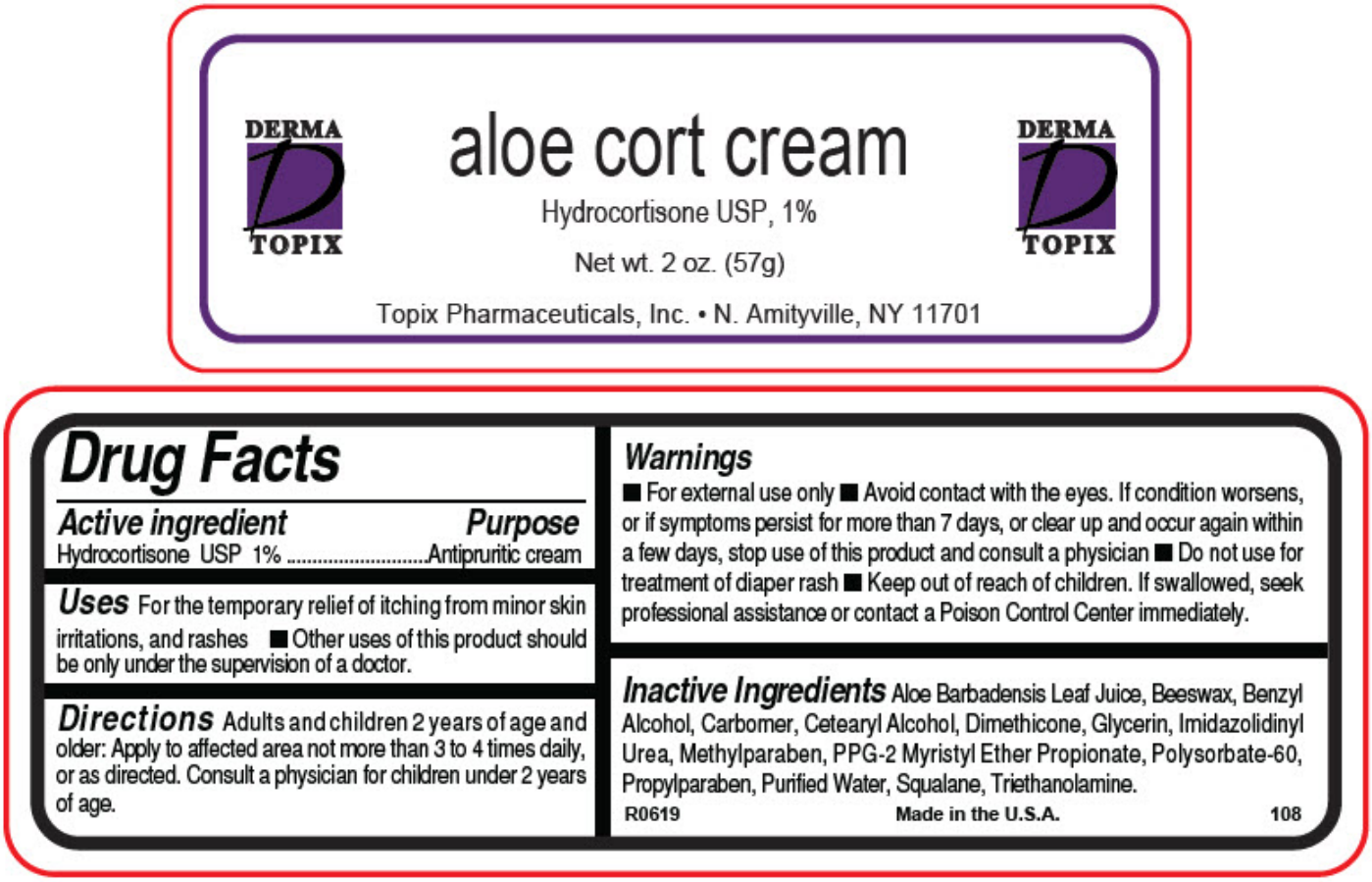
aloe cort cream

Hydrocortisone USP, 1%

Net wt. 2 oz. (57g)

Topix Pharmaceuticals, Inc. • N. Amityville, NY 11701

DERMA
TOPIX



ALOE CORT

hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51326-108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	0.57 g in 57 g

Inactive Ingredients

Ingredient Name	Strength
ALOE (UNII: V5VD430YW9)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
GLYCERIN (UNII: PDC6A3C0OX)	
IMIDUREA (UNII: M629807ATL)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PPG-2 MYRISTYL ETHER PROPIONATE (UNII: 88R97D8U8A)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SQUALANE (UNII: GW89575KF9)	
TROLAMINE (UNII: 9O3K93S3TK)	
DIMETHICONE (UNII: 92RU3N3Y1O)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51326-108-57	57 g in 1 TUBE; Type 0: Not a Combination Product	02/27/1990	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M017	02/27/1990	

Labeler - Topiderm, Inc. (049121643)

Registrant - Topiderm, Inc. (049121643)

Establishment

Name	Address	ID/FEI	Business Operations
Topiderm, Inc.		049121643	MANUFACTURE(51326-108)

Establishment

Name	Address	ID/FEI	Business Operations
Topix Pharmaceuticals, Inc.		117745066	PACK(51326-108)

Revised: 9/2019 Topiderm, Inc.