

SKIN A COOL HYDROCORTISONE ANTI-ITCH- hydrocortisone cream
Ana-Cool, LLC

SKIN A COOL Hydrocortisone Anti-Itch Cream

DRUG FACTS:

Active Ingredients:

Hydrocortisone 1.0%

Purpose

Anti-itch

Uses:

- Temporary relief of skin itching.
- The temporary relief of itching associated with minor skin irritations and rashes.
- Other uses of this product should be only under the advise and supervision of a doctor.

Warnings:

For external use only.

Do not use for

- for the treatment of diaper rash. Consult a doctor.

When using this product

- Avoid contact with the eyes.
- Do not exceed the recommended daily dosage unless directed by a doctor.
- In case of bleeding, consult a doctor promptly.
- Do not put this product into the rectum by using fingers or any mechanical device or applicator.

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 and do not begin use of any other hydrocortisone product unless you have consulted a doctor.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions:

Apply to affected area not more than 3 to 4 times daily. **Adults and children 2 years of age and older:**

Do not use, consult a doctor. **Children under 2 years of age:**

When practical, cleanse the affected area "(selected one or both of the following: with mild soap and warm water and rinse thoroughly". or "by patting or blotting with an appropriate cleansing pad").: **Adults:**

consult a doctor. **Children under 12 years of age:**

Other Information:

Store at 20-25°C (68-77°F)

Inactive ingredients:

Aloe barbadensis (aloe vera gel) juice, aqua (deionized water), C12-15 alkyl benzoate, camellia sinensis (green tea) leaf extract, cetareth-20, cetaryl alcohol, cetyl alcohol, ethylhexylglycerin, glycerin, glyceryl stearate, hamamelis virginiana (witch hazel) extract, helianthus annuus (sunflower) seed oil, PEG-100 stearate, petrolatum, phenoxyethanol, stearyl alcohol, tocopheryl acetate (vitamin E), zemea propanediol.

Questions?

visit: **skin-a-cool.com**

Package Labeling:

TUBE TEMPLATE

108mm

Non Printing Area

Rapid relief for itchy
inflamed, irritated skin

SKIN RASHES
A ECZEMA
BITES
SUNBURN
COOL

Patented Formula

Aloe, Green tea
Vitamin E

MAXIMUM OTC STRENGTH
HYDROCORTISONE
ANTI-ITCH CREAM

NET WT 2 OZ (56.7g)

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Hydrocortisone 1.0%	Anti-itch

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Other Information:

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Inactive ingredients: Aloe barbadensis (aloe vera gel) juice, aqua (deionized water), C12-15 alkyl benzoate, camellia sinensis (green tea) leaf extract, ceteareth-20, cetearyl alcohol, cetyl alcohol, ethylhexylglycerin, glycerin, glyceryl stearate, hamamelis virginiana (witch hazel) extract, helianthus annuus (sunflower) seed oil, PEG-100 stearate, petrolatum, phenoxyethanol, stearyl alcohol, tocopheryl acetate (vitamin E), zemea propanediol.

Questions? visit: skin-a-cool.com

Distributed by:
Ana-Cool LLC
425 County Rd 39A,
Southampton NY 11968



Non Printing Area

FRONT
PANEL

Tube Shoulder

BACK
PANEL

SKIN A COOL HYDROCORTISONE ANTI-ITCH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70288-173
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HAMAMELIS VIRGINIANA TOP (UNII: UDA30A2JJY)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70288-173-00	56.7 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product	03/01/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M017	03/01/2021	

Labeler - Ana-Cool, LLC (091452072)