

**ANA COOL RAPID SOOTHING COOLING FORMULA- hydrocortisone cream**  
**Ana-Cool, LLC**

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**Ana-Cool Rapid Soothing & Cooling Formula**

**DRUG FACTS**

**Active Ingredients:**

Hydrocortisone 1.0%

Anti -itch

**Uses:**

- Temporarily relief of external anal itching
- Temporary relief of itching associated with minor skin irritations and rashes
- 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. Consult a doctor.

**When using this product,**

• avoid contact with the eyes • do not exceed the recommended daily dosage unless directed by a doctor • do not put into the rectum by using fingers or any mechanical device or applicator

**Stop use and ask a doctor if**

• bleeding occurs • condition worsen • symptoms persist for more than 7 days or clear up occur again within a few days. 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 Centre right away

**Directions:**

- cleanse the affected area by patting or blotting with an appropriate cleansing wipe. Gently dry by patting or blotting with tissue or soft cloth before the application of this product **Adults:**

- apply to the affected area not more than 3 to 4 times daily. **Adults and children 12 years of age and older:**
- do not use, consult a doctor **Children under 12 years of age:**

## Other Information

Store at 20 - 25 °C (68-77°F)

## Other Ingredients:

Aloe barbadensis (aloe vera gel) juice, aqua (deionized water), C12-15 alkyl benzoate, camellia sinensis (green tea) leaf extract, cetearcth-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.

## Package Labeling:



# ANA COOL RAPID SOOTHING COOLING FORMULA

hydrocortisone cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70288-714
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>HAMAMELIS VIRGINIANA TOP</b> (UNII: UDA30A2JJY)	
<b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:70288-714-01	1 in 1 BOX	11/25/2015	
1		56.7 g in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	11/25/2015	

