

**HEALING TREE CALMING ANTI-ITCH- hydrocortisone cream**  
**Renu Laboratories, 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.*

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**HEALING TREE CALMING ANTI-ITCH CREAM**

1 Percent Hydrocortisone

Anti-itch Anti-inflammatory

**Uses**

For the temporary relief and aid in reducing redness, itching and irritation associated with eczema, psoriasis, poison oak and ivy, bug bites, rashes, minor burns, abrasions and blemishes

For external use only

Do not use

- for external genital, vaginal or anal itching
- with other hydrocortisone product unless consulted by a doctor
- in or near the eyes
- for diaper rash

**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

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

If pregnant or breastfeeding ask a health professional before use

**KEEP OUT OF REACH OF CHILDREN**

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

HEALING TREE

CALMING

ANTI-ITCH CREAM

NET WT. 59 ml (2.0 fl. oz.)

Directions

- adults and children 2 years of age and older: spray affected area not more than 3 to 4 times daily
- children under 2 years of age: do not use consult a doctor
- to apply to face, spray into palm of hand and gently apply

## Other information

store between 20° to 25° C (68° to 77° F)

Aloe Barbadensis leaf juice (Aloe Vera), Arnica Montana Extract, Calendula Officinalis Extract (Calendula), Carbomer, Cetyl Alcohol,

Commiphora Myrrha Oil (Myrrh), Deionized Water, Glycerin, Glycerol Stearate, Hydrastis Canadensis Root Extract (Goldenseal),

Melaleuca Alternifolia Leaf Oil (Tea Tree), Mentha Piperita Oil (Peppermint), Olea Europaea Oil (Olive), PEG-120 Methyl Glucose

Dioleate, Persea Gratissima Oil (Avocado), Polysorbate 20, Potassium Sorbate, Simmondsia Chinensis Oil (Jojoba), Sodium

Benzoate, Symphytum Officinale Extract (Comfrey) Leaf, Triethanolamine.

Questions? call 800-376-1293

Manufactured for

Healing Tree Essentials

Yamhill, OR 97148

[healingtreenaturals.com](http://healingtreenaturals.com)

## **Multi-layer Label**

Healing Tree Anti-Itch Cream

**CALMING ANTI-ITCH CREAM**  
With Aloe, Calendula & 1% Hydrocortisone for Eczema, Bug Bites and Rashes



**HEALING TREE®**  
NET WT. 59 ml (2.0 fl. oz.)

Manufactured by:  
Healing Tree Essentials  
Yamhill, OR 97148  
healingtreeessentials.com

HEALING TREE® 1-800-376-1293

Pure Ingredients - Powerful Healing

Peel back corner for drug facts information

INSIDE  
TOP  
BASE  
Multi-Layer Label

373518 SS  
PROOF# 02 25  
HP

PEEL CORNER

**INSIDE**

**CALMING ANTI-ITCH CREAM**  
With Aloe, Calendula & 1% Hydrocortisone for Eczema, Bug Bites and Rashes

**Drug Facts**

**Active ingredient** Purpose  
1% Hydrocortisone...Anti-Itch/Anti-Inflammatory

**Uses** For the temporary relief and aid in reducing redness, itching, and irritation associated with eczema, psoriasis, poison oak/ivy, bug bites, rashes, minor burns, abrasions, and blisters.

**Warnings**  
For external use only.  
**Do not use** ■ for external genital, vaginal or anal itching ■ with other hydrocortisone product unless consulted by a doctor ■ in or near the eyes ■ for diaper rash  
**When using this product** ■ avoid contact with the eyes ■ if product gets into the eye, flush with water for 15 minutes  
**Stop use and ask a doctor** ■ condition worsens ■ symptoms persist for more than 7 days or clear up and occur again within a few days  
**Keep out of reach of children.** If swallowed get medical help or contact a Poison Control Center right away.

KEEP OUT OF REACH OF CHILDREN  
If Pregnant or breastfeeding ask a health professional before use.

HINGE SIDE

**= safety region**

**BASE**

**Directions** ■ adults and children 2 years of age and older : spray affected area not more than 3 to 4 times daily ■ children under 2 years of age: do not use, consult a doctor to apply to face, spray into palm of hand and gently apply

**Other information**  
store between 20° to 25°C (68° to 77°F)

**Inactive ingredients** Aloe Barbodensis leaf Juice, Aloe Vera, Annica Montana Extract, Calendula Officinalis Extract (Calendula), Carbomer, Cetyl Alcohol, Commiphora Myrrha Oil (Myrrh), Deionized Water, Glycerin, Glyceryl Stearate, Hydrazis Canadensis Root Extract (Goldenseal), Melissa Alemaifolia Leaf Oil (Tea Tree), Mentha Piperita Oil (Peppermint), Olea Europaea Oil (Olive), PEG-120 Methyl Glucose Diolate, Persea Gratissima Oil (Avocado), Polysorbate 20, Potassium Sorbate, Simmondsia Chinensis Oil (Jojoba), Sodium Benzoate, Symphytum Officinale Extract (Comfrey) Leaf, Triethanolamine.

**Questions?** call 800-376-1293

**Manufactured by:**  
Healing Tree Essentials  
Yamhill, OR 97148  
healingtreeessentials.com

HINGE SIDE

**HEALING TREE CALMING ANTI-ITCH**

hydrocortisone cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:76348-804
<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	0.59 mg in 59 mL

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>MYRRH OIL</b> (UNII: H74221J5J4)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>MELALEUCA ALTERNIFOLIA (TEA TREE) LEAF OIL</b> (UNII: VIF565UC2G)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>PEG-120 METHYL GLUCOSE DIOLEATE</b> (UNII: YM0K64F20V)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>AVOCADO OIL</b> (UNII: 6VNO72PFC1)	
<b>OLIVE OIL</b> (UNII: 6UYK2W1W1E)	
<b>CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE</b> (UNII: 0A5MM307FC)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CALENDULA OFFICINALIS FLOWER</b> (UNII: P0M7O4Y7YD)	
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)	
<b>GOLDENSEAL</b> (UNII: ZW3Z11D0JV)	
<b>COMFREY</b> (UNII: D05HXX6R3G)	
<b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:76348-804-06	1 in 1 BOX	05/26/2023	
1	NDC:76348-804-05	59 mL in 1 BOTTLE, PLASTIC; 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 not final	part348	05/26/2023	

## Establishment

Name	Address	ID/FEI	Business Operations
Renu Laboratories, Inc.		945739449	manufacture(76348-804)

Revised: 5/2023

Renu Laboratories, Inc.