

# **HYDROCORTISONE WITH ALOE- hydrocortisone with aloe anti itch cream NeilMed Pharmaceuticals Inc.**

-----

## **NeilMed Hydrocortisone 1% Cream with Aloe Anti-Itch**

### **Drug Facts**

Active Ingredients Hydrocortisone, USP 1%

### **Purpose**

Anti-itch

### **Uses:**

for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to: ■ eczema ■ insect bites ■ poison ivy ■ poison oak ■ poison sumac ■ soaps  
■ jewelry ■ detergents ■ cosmetics ■ psoriasis ■ seborrheic dermatitis ■ for external genital, feminine and anal itching ■ 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 external feminine itching if you have a vaginal discharge. Consult a doctor. ■ for the treatment of diaper rash. Consult a doctor.

### **When using this product**

■ avoid contact with the eyes ■ do not begin the use of any other hydrocortisone product unless directed by a doctor ■ for external anal itching: ■ do not use more than directed unless directed by a doctor ■ do not put this product into the rectum by using fingers or any mechanical device or applicator.

### **Stop use and ask a doctor if**

■ symptoms last for more than 7 days. ■ the condition gets worse ■ symptoms clear up and occur again in a few days ■ rectal bleeding occurs, consult doctor promptly.

### **Keep out of reach of children**

If swallowed, get medical help or contact a Poison Control Center right away. 1-800-222-1222

## 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 If pregnant or breast-feeding ■ ask a health professional before use.

For external anal itching Adults: when practical, clean the affected area with mild soap and warm water, rinse thoroughly, gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product Children under 12 years of age: consult a doctor

## Other information:

- Storage temperature: not to exceed 30°C (86°F). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

## Inactive ingredients:

Aloe vera concentrate, benzyl alcohol, cetareth 20, cetearyl alcohol, cetyl palmitate, glyceryl, isopropyl myristate, isostearyl neopentanoate, methylparaben, peg-40 stearate, purified water. May contain citric acid or sodium citrate solution to adjust pH.

TAMPER EVIDENT DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING

**Drug Facts**

**Active Ingredients:** Hydrocortisone, USP 1% **Purpose:** Anti-itch

**Uses:** for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:

- eczema
- insect bites
- poison ivy
- poison oak
- poison sumac
- soaps
- jewelry
- detergents
- cosmetics
- psoriasis
- seborrheic dermatitis
- for external genital, feminine and anal itching
- other uses of this product should be only under the advice and supervision of a doctor

**Drug Facts (continued)**

**Warnings:**

**For external use only**

**Do not use**

- for external feminine itching if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

**When using this product**

- avoid contact with the eyes
- do not begin the use of any other hydrocortisone product unless directed by a doctor
- for external anal itching: do not use more than directed unless directed by a doctor
- do not put this product into the rectum by using fingers or any mechanical device or applicator.

**Stop use and ask a doctor if**

- symptoms last for more than 7 days.
- the condition gets worse

7 05928 15003 4

NeilMed  
Manufactured by  
NeilMed Pharmaceuticals, Inc.  
10000 W. 10th Ave., Suite 100  
Denver, CO 80202  
© 2014 NeilMed Pharmaceuticals, Inc.  
PNE1010401

NET WT 2 OZ (56 g)

**NeilMed**  
Hydrocortisone 1% Cream with Aloe  
**ANTI-ITCH**

Soothing relief from itching, rashes, redness, inflammation and other skin irritations.

**NeilMed**  
Hydrocortisone 1% Cream with Aloe  
**ANTI-ITCH**

**Drug Facts (continued)**

- symptoms clear up and occur again in a few days
- rectal bleeding occurs, consult doctor promptly

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away. 1-800-222-1222

**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

**If pregnant or breast-feeding** ■ ask a health professional before use.

**For external anal itching**

Adults: when practical, clean the affected area with mild soap and warm water, rinse thoroughly,

**Drug Facts (continued)**

gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product Children under 12 years of age: consult a doctor

**Other information**

- Storage temperature: not to exceed 30°C (86°F). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

**Inactive ingredients:** aloe vera concentrate, benzyl alcohol, cetareth 20, cetearyl alcohol, cetyl palmitate, glyceryl, isopropyl myristate, isostearyl neopentanoate, methylparaben, peg-40 stearate, purified water. May contain citric acid or sodium citrate solution to adjust pH.

**Questions? 1 (877) 477-8633**

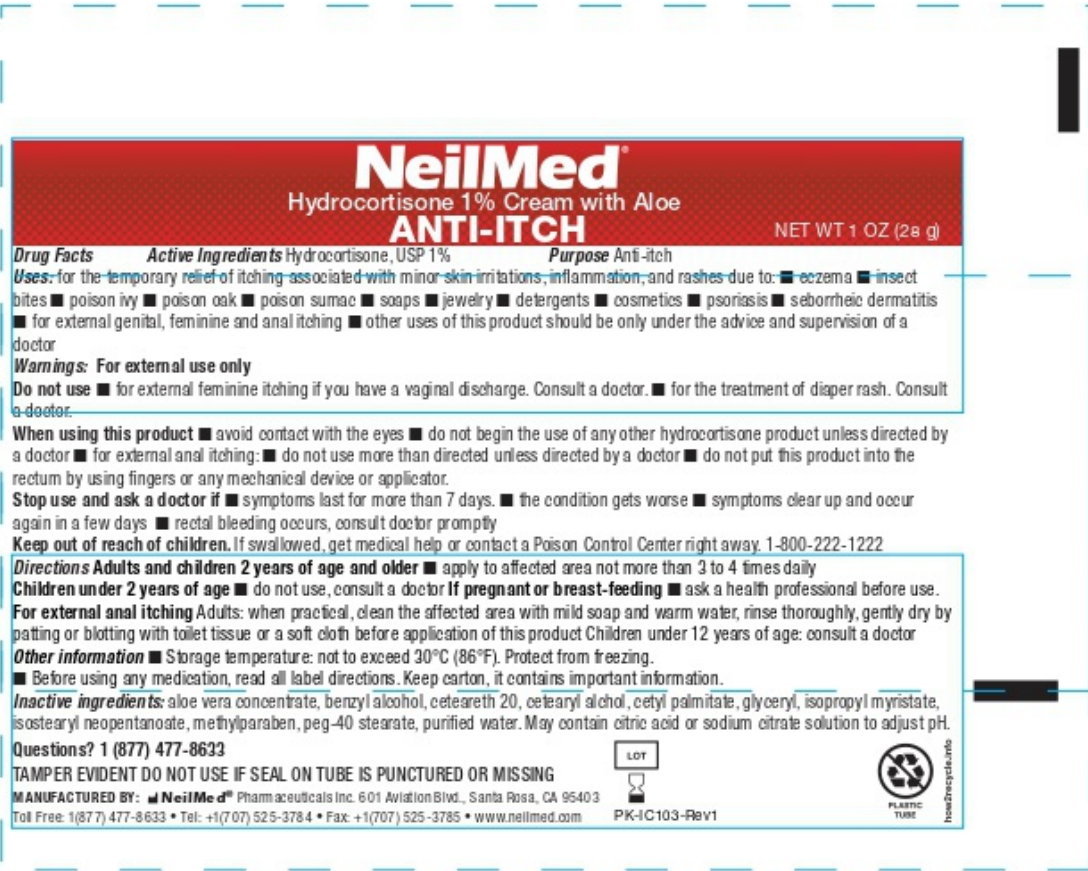
TAMPER EVIDENT DO NOT USE IF SEAL ON TUBE IS PUNCTURED OR MISSING

**NeilMed**  
Hydrocortisone 1% Cream with Aloe  
**ANTI-ITCH**

NET WT 2 OZ (56 g)

 **LEARN MORE**

Soothing relief from itching, rashes, redness, inflammation and other skin irritations.



Proposed 7\_5 - WIC 912561 - Hydrocortisone\_Cream\_USP\_1%\_1oz Tube.pdf

**HYDROCORTISONE WITH ALOE**

hydrocortisone with aloe anti itch cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:13709-317
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	10.2 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
-----------------	----------

<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ISOPROPYL MYRISTATE</b> (UNII: ORE8K4LNJS)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)	
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>ISOSTEARYL NEOPENTANOATE</b> (UNII: 411THY156Q)	
<b>PEG-40 MONOSTEARATE</b> (UNII: ECU18C66Q7)	
<b>CETYL PALMITATE</b> (UNII: 5ZA2S6B08X)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-317-01	1 in 1 CARTON	08/18/2023	
1		28 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:13709-317-02	1 in 1 CARTON	08/18/2023	
2		56 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M015	08/18/2023	

**Labeler** - NeilMed Pharmaceuticals Inc. (799295915)

### Establishment

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals Inc.		799295915	manufacture(13709-317)

Revised: 6/2024

NeilMed Pharmaceuticals Inc.