

## **HYDROCORTISONE WITH ALOE- hydrocortisone with aloe anti itch cream NeilMed Pharmaceuticals 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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### **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** 1

**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)** 2

**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

Manufactured by  
**NeilMed**  
10000 W. 15th Street, Omaha, NE 68130  
Tel: 402-426-7000  
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PHARMACY INFORMATION  
NEILMED

**NeilMed**  
Hydrocortisone 1%  
Cream with Aloe

**ANTI-ITCH**

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



NET WT 2 OZ (56 g)

**NeilMed**  
Hydrocortisone 1%  
Cream with Aloe

**ANTI-ITCH**

**Drug Facts (continued)** 3

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

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**Directions**  
Adults and children 2 years of age and older ■ apply to affected area not more than 3 to 4 times daily

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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)** 4

gently dry by patting or blotting with toilet tissue or a soft cloth before application of this product  
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**Questions? 1 (877) 471-8633**

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**NeilMed**  
Hydrocortisone 1%  
Cream with Aloe

**ANTI-ITCH**

NET WT 2 OZ (56 g)



Aloe



LEARN MORE

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

**NeilMed**  
Hydrocortisone 1% Cream with Aloe  
**ANTI-ITCH** NET WT 1 OZ (28 g)

**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.

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**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

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**Directions** Adults and children 2 years of age and older apply to affected area not more than 3 to 4 times daily  
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**Questions?** 1 (877) 477-8633

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## 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: W4X0X7BP) (HYDROCORTISONE - UNII:W4X0X7BP)	HYDROCORTISONE	10.2 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
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<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BENZYL ALCOHOL</b> (UNII: LKG8494WBH)	
<b>ISOPROPYL MYRISTATE</b> (UNII: 0RE8K4LNJS)	
<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 not final	part348	08/18/2023	

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

### Establishment

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

Revised: 8/2023

NeilMed Pharmaceuticals Inc.