# 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

 $\blacksquare$  jewelry  $\blacksquare$  detergents  $\blacksquare$  cosmetics  $\blacksquare$  psoriasis  $\blacksquare$  seborrheic dermatitis  $\blacksquare$  for external genital, feminine and anal itching  $\blacksquare$  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

 $\blacksquare$  symptoms last for more than 7 days.  $\blacksquare$  the condition gets worse  $\blacksquare$  symptoms clear up and occur again in a few days  $\blacksquare$  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  $\blacksquare$  do not use, consult a doctor If pregnant or breast-feeding  $\blacksquare$  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:

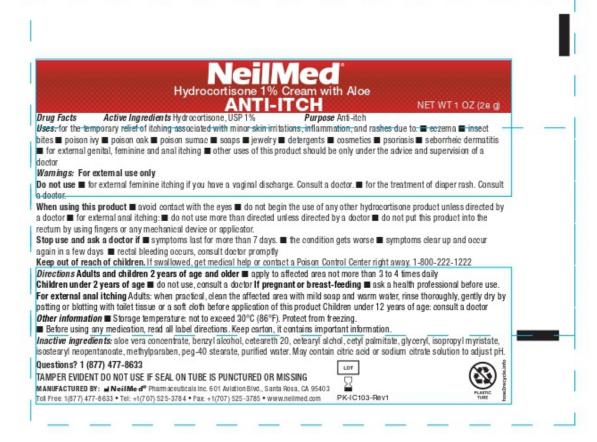
- Storage temperature: not to exceed 30°C (86°F). Protect from freezing.
- Before using any medication, read all label directions. Keep carton, it contains important information.

### Inactive ingredients:

Aloe vera concentrate, benzyl alcohol, ceteareth 20, cetearyl alchol, 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





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

#### HYDROCORTISONE WITH ALOE

hydrocortisone with aloe anti itch cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-317
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
HYDROCORTISONE (UNII: W4X0X7BPI) (HYDROCORTISONE - UNII:W4X0X7BPI)	HYDROCORTISONE	10.2 mg in 1 g		

	Inactive Ingredients	
ı	Ingredient Name	Strength

ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
WATER (UNII: 059QF0KO0R)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)	
PEG-40 MONOSTEARATE (UNII: ECU18C66Q7)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
GLYCERIN (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.