

**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, cetaryl 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

<p>Drug Facts</p> <p>Active Ingredients: Hydrocortisone, USP 1% Purpose: Anti-itch</p> <p>Uses: for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:</p> <table style="width: 100%; border: none;"> <tr> <td>■ eczema</td> <td>■ insect bites</td> <td>■ poison ivy</td> </tr> <tr> <td>■ poison oak</td> <td>■ poison sumac</td> <td>■ soaps</td> </tr> <tr> <td>■ jewelry</td> <td>■ detergents</td> <td>■ cosmetics</td> </tr> <tr> <td>■ psoriasis</td> <td>■ seborrheic dermatitis</td> <td></td> </tr> </table> <p>■ for external genital, feminine and anal itching</p> <p>■ other uses of this product should be only under the advice and supervision of a doctor</p>	■ eczema	■ insect bites	■ poison ivy	■ poison oak	■ poison sumac	■ soaps	■ jewelry	■ detergents	■ cosmetics	■ psoriasis	■ seborrheic dermatitis		<p>Drug Facts (continued)</p> <p>Warnings:</p> <p>For external use only</p> <p>Do not use</p> <ul style="list-style-type: none"> ■ for external feminine itching if you have a vaginal discharge. Consult a doctor. ■ for the treatment of diaper rash. Consult a doctor. <p>When using this product</p> <ul style="list-style-type: none"> ■ 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. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ■ symptoms last for more than 7 days. ■ the condition gets worse
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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.

NeilMed[®]

Hydrocortisone 1% Cream with Aloe

ANTI-ITCH

NET WT 1 OZ (28 g)

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Questions? 1 (877) 477-8633

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MANUFACTURED BY: ■ NeilMed[®] Pharmaceuticals Inc. 601 Aviation Blvd., Santa Rosa, CA 95403
Toll Free: 1(877) 477-8633 • Tel: +1(707) 525-3784 • Fax: +1(707) 525-3785 • www.neilmed.com

LOT

PK-1C103-R8v1

PLASTIC TUBE
how2recycle.com

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

Inactive Ingredients

Ingredient Name	Strength
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ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
ISOPROPYL MYRISTATE (UNII: ORE8K4LNJS)	
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 Drug	M017	08/18/2023	

Labeler - NeilMed Pharmaceuticals Inc. (799295915)

Establishment

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

Revised: 7/2024

NeilMed Pharmaceuticals Inc.