

HYDROCORTISONE- cool relief gel with aloe gel **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.

Drug Facts

Active Ingredients

Hydrocortisone 1%

Drug Facts

Purpose : Anti-itch

Drug Facts

Uses:

■ temporarily relieves itching associated with minor skin irritations, inflammation and rashes due to: ■ eczema ■ psoriasis ■ poison ivy, oak and sumac ■ insect bites ■ detergents ■ jewelry ■ cosmetics ■ soaps ■ seborrheic dermatitis ■ temporarily relieves external anal and genital itching ■ other uses of this product should only be under the advise and supervision of a doctor

Warnings: For external use only

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Do not use

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- in the genital area if you have a vaginal discharge. Consult a doctor.
- for the treatment of diaper rash. Consult a doctor.

When using this product

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■ avoid contact with eyes ■ do not use more than directed unless told to do so by a doctor ■ do not put directly into the rectum by using fingers or any mechanical device or applicator

Stop use and ask a doctor if

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, and do not begin use of any other hydrocortisone product unless you have asked a doctor. ■ rectal bleeding occurs

Keep out of reach of children

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

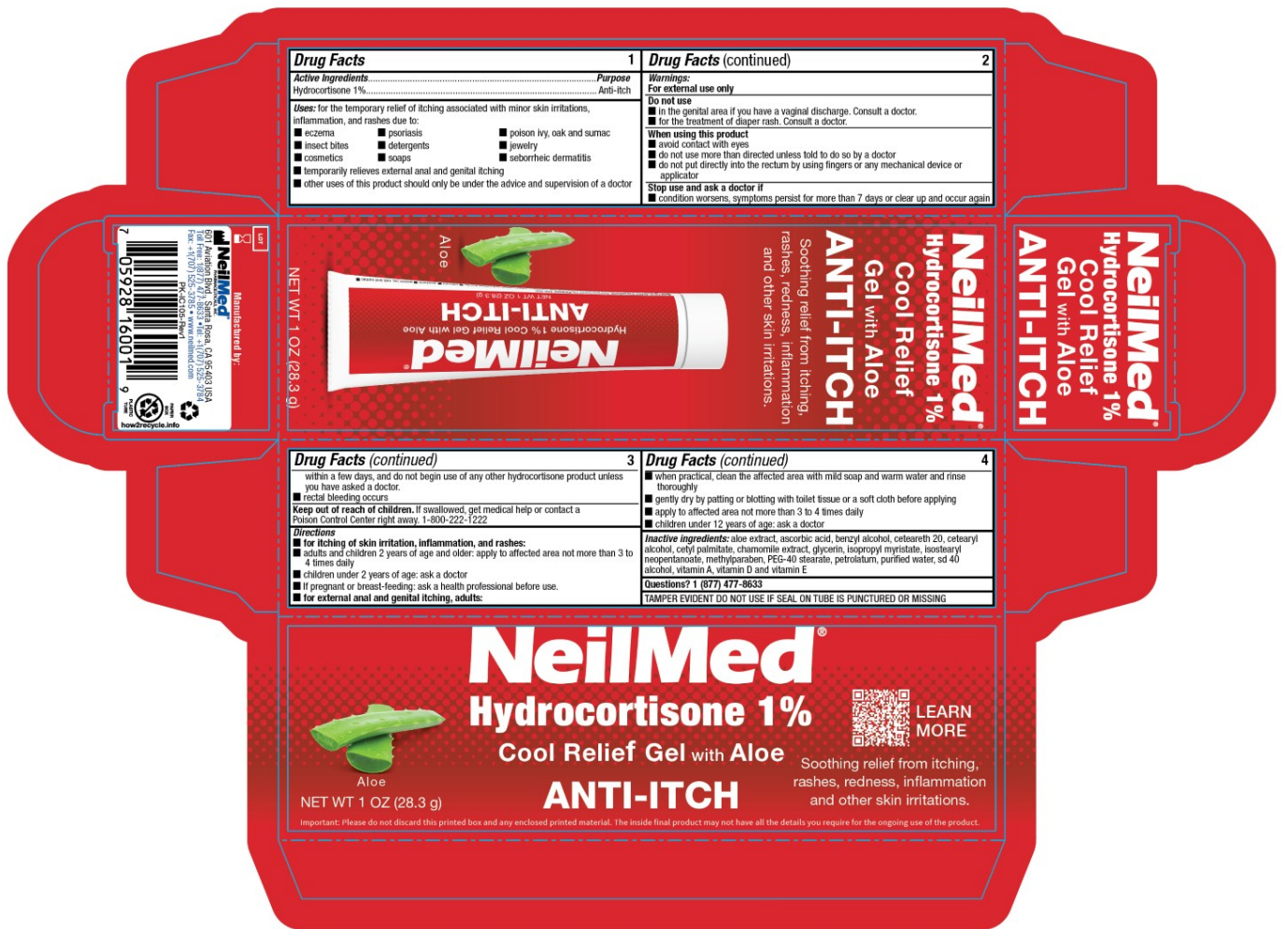
Directions

Directions ■ for itching of skin irritation, inflammation, and rashes: ■ 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: ask a doctor ■ If pregnant or breast-feeding: ask a health professional before use. ■ for external anal and genital itching, adults: ■ when practical, clean the affected area with mild soap and warm water and rinse thoroughly ■ gently dry by patting or blotting with toilet tissue or a soft cloth before applying ■ apply to affected area not more than 3 to 4 times daily ■ children under 12 years of age: ask a doctor

Inactive ingredients:

Aloe extract, ascorbic acid, benzyl alcohol, cetareth 20, cetaryl alcohol, cetyl palmitate, chamomile extract, glycerin, isopropyl myristate, isostearyl neopentanoate, methylparaben, PEG-40 stearate, petrolatum, purified water, sd 40 alcohol, vitamin A, vitamin D and vitamin E

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



HYDROCORTISONE

cool relief gel with aloe gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:13709-318
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
PEG-40 MONOSTEARATE (UNII: ECU18C66Q7)	

GLYCERIN (UNII: PDC6A3C0OX)
METHYLPARABEN (UNII: A2I8C7HI9T)
ISOSTEARYL NEOPENTANOATE (UNII: 411THY156Q)
VITAMIN D (UNII: 9VU1KI44GP)
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)
CHAMOMILE (UNII: FGL3685T2X)
PETROLATUM (UNII: 4T6H12BN9U)
WATER (UNII: 059QF0KO0R)
VITAMIN A (UNII: 81G40H8B0T)
ALCOHOL (UNII: 3K9958V90M)
TOCOPHEROL (UNII: R0ZB2556P8)
ALOE (UNII: V5VD430YW9)
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-318-01	1 in 1 CARTON	08/21/2023	
1		28 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	08/21/2023	

Labeler - NeilMed Pharmaceuticals Inc (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals Inc		799295915	manufacture(13709-318)

Revised: 8/2023

NeilMed Pharmaceuticals Inc