ANTI ITCH- hydrocortisone gel
Neilmed Pharmaceuticals Inc.

Drug Facts

Active Ingredients
Hydrocortisone 1%

Drug Facts

Active Ingredients.....Purpose
Hydrocortisone 1%..... Anti-itch

Uses

Uses: for the temporary relief of itching associated with minor skin irritations, inflammation, and rashes due to:
■ eczema
■ insect bites
■ cosmetics
■ psoriasis
■ detergents
■ soaps
■ poison ivy, oak and sumac
■ jewelry
■ seborrheic dermatitis

■ temporarily relieves external anal and genital itching
■ other uses of this product should only be under the advice and supervision of a doctor

Do not Use

- 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

- 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

■ 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

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

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 leaf, avena sativa extract, dextrin, dimethicone, disodium EDTA, glycerin, hydroxyethyl acrylate/sodium acrylodimethyl taurate copolymer, isohexadecane, maltodextrin, methyl gluceth-20, methyl lactate, methylparaben, polysorbate 60, PPG-3 benzyl ether myristate, propylparaben, purified water, SD alcohol,sodium citrate

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

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

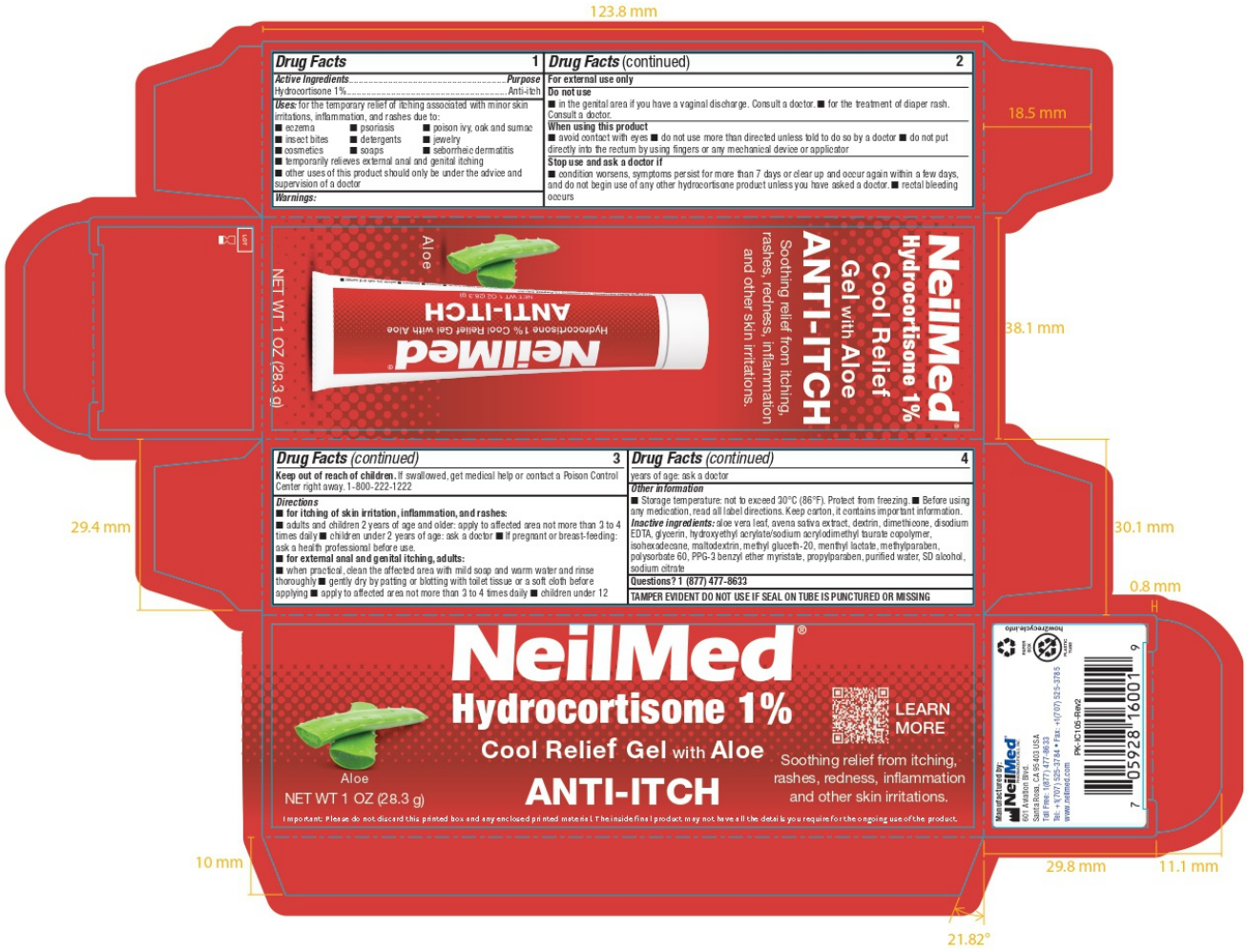
■ children under 2 years of age: ask a doctor

■ 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

Warnings

For external use only.

Do not use
■ in the genital area if you have a vaginal discharge. Consult a doctor. ■ for the treatment of diaper rash.
Consult a doctor.



ANTI ITCH

hydrocortisone gel

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:13709-326
Route of Administration	RECTAL		

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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
AVENA SATIVA POLLEN (UNII: A7IKY24TR7)	
ICODEXTRIN (UNII: 2NX48Z0A9G)	
HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (45000 MPA.S AT 1%) (UNII: 86FQE96TZ4)	
MENTHYL LACTATE, (-)- (UNII: 2BF9E65L7I)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
PPG-3 BENZYL ETHER MYRISTATE (UNII: 8075L58MKO)	
DIMETHICONE 1000 (UNII: MCU2324216)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
GLYCERIN (UNII: PDC6A3C0OX)	
DEHYDRATED ALCOHOL (UNII: 3K9958V90M)	
WATER (UNII: 059QF0KO0R)	
ISOHEXADECANE (UNII: 918X1OUF1E)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
METHYL GLUCETH-20 (UNII: J3QD0LD11P)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13709-326-01	1 in 1 CARTON	05/21/2024	
1		28.3 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	05/21/2024	

Labeler - Neilmed Pharmaceuticals Inc. (799295915)

Establishment

Name	Address	ID/FEI	Business Operations
NeilMed Pharmaceuticals Inc.		799295915	manufacture(13709-326)

Revised: 4/2024 Neilmed Pharmaceuticals Inc.