### THERA PLUS ANTI-ITCH WITH ALOE HYDROCORTISONEhydrocortisone cream Fourstar Group USA, Inc.

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### Thera plus Anti-itch cream with aloe Hydrocortisone cream

#### **Drug Facts**

#### **Active ingredients**

Hydrocortisone 1%

#### **Purpose**

Anti-itch

#### Uses

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

### 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.

# 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 persists for more than 7 days or clear up and occur again within a few days, and do not begin use any other hydrocortisone product unless you have asked a doctor
- rectal bleeding occurs

### Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

#### **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
- 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 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

#### Other information

- store at room temperature 68°-77°F (20°-25°C).
- tamper-evident: do not use if foil seal is broken or missing.

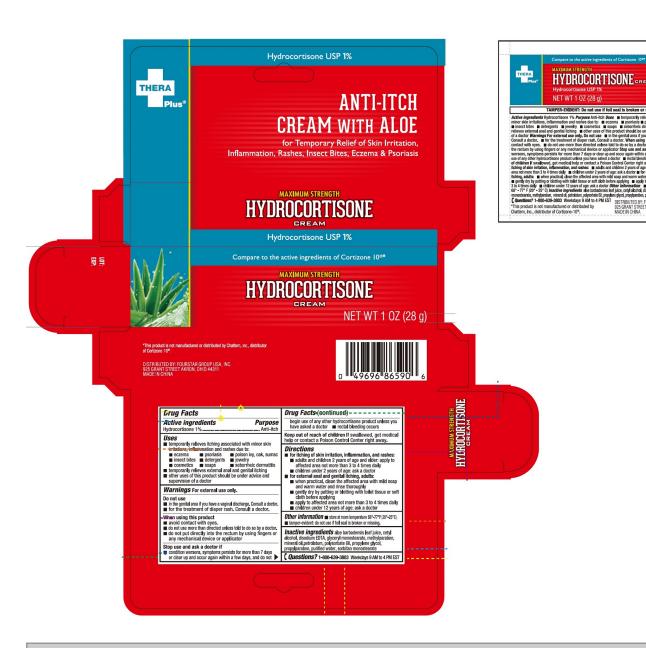
# Inactive ingredients

aloe barbadensis leaf juice, cetyl alcohol, disodium EDTA, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polysorbate 60, propylene glycol, propylparaben, purified water, sorbitan monostearate

#### **Questions?**

1-800-639-3803 Weekdays 9 AM to 4 PM EST

# Package Labeling:



#### THERA PLUS ANTI-ITCH WITH ALOE HYDROCORTISONE

hydrocortisone cream

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:80684-038

**Route of Administration** TOPICAL

### **Active Ingredient/Active Moiety**

Ingredient Name Basis of Strength Strength

HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ) HYDROCORTISONE 10 mg in 1 g

#### **Inactive Ingredients**

Ingredient Name	Strenath

ALOE VERA LEAF (UNII: ZY81Z83H0X)
CETYL ALCOHOL (UNII: 936|ST6|CN)

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

P	Packaging					
#	Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:80684-038- 01	1 in 1 BOX	01/30/2022			
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 Drug	M017	01/30/2022		

# Labeler - Fourstar Group USA, Inc. (140099503)

Revised: 10/2023 Fourstar Group USA, Inc.