

**THERA PLUS ANTI-ITCH WITH ALOE HYDROCORTISONE-
hydrocortisone cream
Fourstar Group USA, Inc.**

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:



*This product is not manufactured or distributed by Chatten, Inc., distributor of Cortizone 10®.

DISTRIBUTED BY: FOURSTAR GROUP USA, INC.
825 GRANT STREET AKRON, OHIO 44311
MADE IN CHINA



Drug Facts		Drug Facts (continued)	
Active ingredients Hydrocortisone 1%	Purpose Anti-itch	begin use of any other hydrocortisone product unless you have asked a doctor ■ rectal bleeding occurs	
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		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	
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		Other information ■ store at room temperature 68°-77°F (20°-29°C) ■ tamper-evident: do not use if foil seal is broken or missing.	
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		Inactive ingredients aloe barbadensis leaf juice, cetyl alcohol, disodium EDTA, glyceryl monostearate, methylparaben, mineral oil, petrolatum, polyorbate 60, propylene glycol, propylparaben, purified water, sorbitan monostearate	
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THERA PLUS ANTI-ITCH WITH ALOE HYDROCORTISONE

hydrocortisone cream

Product Information

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	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
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)	

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.