

**FREDS HYDROCORTISONE PLUS 12 MOISTURIZERS- hydrocortisone cream
FRED'S, 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.

**Fred's Hydrocortisone Cream 1%
Plus 12 Moisturizers**

Drug Facts

Active ingredient

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 only be under the 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 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. 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 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

Other information

- To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube
- Store at 20° to 25° C (68° to 77° F)
- See carton or tube crimp for lot number and expiration date

Inactive ingredients

aloe barbadensis, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, chamomile (anthesis nobilis) oil, citric acid, corn (zea mays) oil, glycerin, glyceryl stearate, isopropyl palmitate, maltodextrin, methylparaben, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

Questions?

Call **1-866-923-4914**

DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD,
MEMPHIS, TN 38118

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

MAXIMUM STRENGTH

Hydrocortisone
Cream 1%

Antipruritic (Anti-Itch)
Itch and Rash Relief

- Dry, Itchy Skin
- Skin Irritation & Rashes
- Eczema & Psoriasis
- Moisturizes while it Relieves
- Enriched with Aloe

Plus 12 Moisturizers

NET WT 1 oz (28.4g)

Enriched With Vitamins A, D & E



FREDS HYDROCORTISONE PLUS 12 MOISTURIZERS			
hydrocortisone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-182

Route of Administration	TOPICAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	1 g in 100 g	
Inactive Ingredients				
	Ingredient Name	Strength		
	cetostearyl alcohol (UNII: 2DMT128M1S)			
	sodium lauryl sulfate (UNII: 368GB5141J)			
	sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)			
	chamomile flower oil (UNII: 60F80Z61A9)			
	citric acid monohydrate (UNII: 2968PHW8QP)			
	corn oil (UNII: 8470G57WFM)			
	glycerin (UNII: PDC6A3C0OX)			
	glyceryl monostearate (UNII: 230OU9XXE4)			
	isopropyl palmitate (UNII: 8CRQ2TH63M)			
	maltodextrin (UNII: 7CVR7L4A2D)			
	methylparaben (UNII: A2I8C7HI9T)			
	mineral oil (UNII: T5L8T28FGP)			
	paraffin (UNII: I9O0E3H2ZE)			
	petrolatum (UNII: 4T6H12BN9U)			
	propylene glycol (UNII: 6DC9Q167V3)			
	propylparaben (UNII: Z8IX2SC1OH)			
	water (UNII: 059QF0K00R)			
	stearyl alcohol (UNII: 2KR89I4HIY)			
	Vitamin A palmitate (UNII: 1D1K0N0VVC)			
	cholecalciferol (UNII: 1C6V77QF41)			
	.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)			
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-182-56	1 in 1 CARTON	11/15/2018	
1		28.4 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	11/15/2018	

Labeler - FRED'S, INC. (005866116)