# FREDS HYDROCORTISONE WITH ALOE- 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.

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## Fred's Hydrocortisone Cream 1% with Aloe

**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 be only 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 room temperature
- see carton or tube crimp for lot number and expiration date

### **Inactive ingredients**

aloe powder, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, citric acid, glycerin, glyceryl monostearate, methylparaben, mineral oil, paraffin wax, propylparaben, purified water, sodium lauryl sulfate, stearyl alcohol

#### 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

fred's Pharmacy

NDC 55315-181-56

Compare to the Active Ingredient in Cortizone•10®\*

#### MAXIMUM STRENGTH

Hydrocortisone Cream 1% Antipruritic (Anti-Itch) Itch and Rash Relief

- Eczema & Psoriasis
- Seborrheic Dermatitis
- Insect Bites & Poison Ivy
- External Genital & Anal Itching

• Skin Irritation & Rashes

With Healing Aloe

NET WT 1 oz (28.4g)



#### FREDS HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information					
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-181		
Route of Administration	TOPICAL				

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydro c o rtis o ne	1 g in 100 g		

Inactive Ingredients		
Ingredient Name	Strength	
cetostearyl alcohol (UNII: 2DMT128M1S)		
sodium lauryl sulfate (UNII: 368GB5141J)		
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)		
citric acid monohydrate (UNII: 2968PHW8QP)		
glycerin (UNII: PDC6A3C0OX)		
glyceryl monostearate (UNII: 230 O U9 XXE4)		
methylparaben (UNII: A218 C7H19 T)		
mineral oil (UNII: T5L8T28FGP)		
paraffin (UNII: 1900E3H2ZE)		
propylparaben (UNII: Z8IX2SC1OH)		
water (UNII: 059QF0KO0R)		
stearyl alcohol (UNII: 2KR89I4H1Y)		

Packaging					
# Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>		
1 NDC:55315-181-56	1 in 1 CARTON	11/15/20 18			
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	11/15/20 18			

## **Labeler** - FRED'S, INC. (005866116)

Revised: 11/2018 FRED'S, INC.