

**FAMILY WELLNESS- hydrocortisone 1% cream**  
**FRONT PHARMACEUTICAL PLC**

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**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 •saborrheic dermatitis
- temporarily relieves external 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 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 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

. If swallowed, get medical **Keep out of reach of children** help or contact a Poison Control Center right away.

**Directions**

- for itching or 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 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)

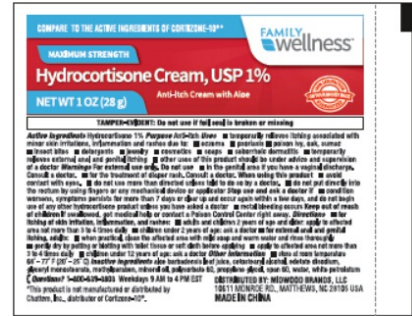
aloe barbadensis leaf juice, **Inactive ingredients**

ceteastrearyl alcohol, edetate disodium, glyceryl

monostearate, methylparaben, mineral oil, polysorbate

60, propylene glycol, span 60, water, white petrolatum

1-800-638-3800 Weekdays 0 AM to 4 PM EST **Questions?**



# FAMILY WELLNESS

hydrocortisone 1% cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69571-009
<b>Route of Administration</b>	TOPICAL		

## 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)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITAN MONOSTEARATE (UNII: NVZ4I0H58X)	

<b>WATER</b> (UNII: 059QF0KO0R)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69571-009-01	1 in 1 CARTON	06/18/2017	
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	06/18/2017	

**Labeler** - FRONT PHARMACEUTICAL PLC (530897792)

### Establishment

Name	Address	ID/FEI	Business Operations
FRONT PHARMACEUTICAL PLC		530897792	manufacture(69571-009)

Revised: 10/2023

FRONT PHARMACEUTICAL PLC