

HYDROCORTISONE WITH ALOE- hydrocortisone cream
Sun Pharmaceutical Industries, Inc.

Hydrocortisone 1% with Aloe

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch cream

Uses

- temporary relief of itching associated with minor skin irritations and rashes due to
 - eczema
 - insect bites
 - poison ivy, poison oak, or poison sumac
 - soaps
 - detergents
 - cosmetics
 - jewelry
 - seborrheic dermatitis
 - psoriasis
 - external genital and anal 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 eyes
- by putting this product into the rectum by using fingers or any mechanical device or applicator

Ask a doctor before use if you have

- a vaginal discharge
- rectal bleeding
- diaper rash

When using this product consult a doctor before exceeding recommended dosage

Stop use and ask a doctor if

- condition gets worse
- condition persists for more than 7 days
- condition clears up and occurs again within a few days. Do not begin to use any other hydrocortisone product unless you have consulted a doctor.

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

Directions

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: do not use. consult a doctor

For external anal itching:

- Adults: when practical, cleanse 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 application of this product

Children under 12 years of age: consult 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 barbadensis, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, citric acid, glycerin, glyceryl stearate, methylparaben, mineral oil, paraffin, propylparaben, purified water, stearyl alcohol

Questions?

Call 1-866-923-4914

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Itch and Rash Relief

MAXIMUM STRENGTH

HYDROCORTISONE WITH ALOE

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2013
Route of Administration	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
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51672-2013-1	1 in 1 CARTON	08/23/1995	
1		14.2 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2013-2	1 in 1 CARTON	08/23/1995	
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:51672-2013-3	1 in 1 CARTON	07/17/2020	
3		60 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M017	08/23/1995	

Labeler - Sun Pharmaceutical Industries, Inc. (146974886)

Establishment

Name	Address	ID/FEI	Business Operations
Sun Pharma Canada Inc.		243339023	manufacture(51672-2013)

Revised: 7/2025

Sun Pharmaceutical Industries, Inc.