HYDROCORTISONE WITH ALOE- hydrocortisone cream 1% cream Taro Phamaceuticals U.S.A., Inc.

Hydrocortisone Cream 1% with Aloe

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

- temporarily relieves of itching associated with minor skin irritations, inflammation, and rashes due to
 - eczema
 - insect bites
 - poison ivy
 - o poison oak
 - o poison sumac
 - soaps
 - detergents
 - cosmetics
 - jewelry
 - seborrheic dermatitis
 - psoriasis
- 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

- do not use if seal on the tube is damaged or is not visible. To open, unscrew cap, pull tab to remove foil seal
- store at room temperature 68-77°F (20°-25°C)
- see crimp of tube or carton for Lot Number and Expiry Date

Inactive ingredients

Aloe Vera Extract, Cetostearyl Alcohol, Glyceryl Monostearate SE, Kathon CG, Propylene Glycol, Purified Water, Stearic Acid, Trolamine, White Petrolatum

Questions or Comments?

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

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

Manufactured in India

MH/DRUGS/28-KD/503

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

MAXIMUM STRENGTH Hydrocortisone Cream 1% Soothing Aloe Cream NET WT 1 oz (28.4 g)



HYDROCORTISONE WITH ALOE

hydrocortisone cream 1% cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-5330
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)		
METHYLCHLOROISOTHIAZOLINONE/METHYLISOTHIAZOLINONE MIXTURE (UNII: 1509QS218W)		
GLYCERYL MONOSTEARATE (UNII: 2300U9XXE4)		
WATER (UNII: 059QF0KO0R)		
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)		
WHITE PETROLATUM (UNII: B6E5W8RQJ4)		
TROLAMINE (UNII: 903K93S3TK)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
ALOE VERA LEAF (UNII: ZY81Z83H0X)		

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:51672- 5330-1	1 in 1 CARTON	03/26/2025		
1		14.2 g in 1 TUBE; Type 0: Not a Combination Product			
2	NDC:51672- 5330-2	1 in 1 CARTON	03/26/2025		
2		28.4 g in 1 TUBE; Type 0: Not a Combination Product			
3	NDC:51672- 5330-3	1 in 1 CARTON	03/26/2025		
3		60 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	03/26/2025	

Labeler - Taro Phamaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
GOPALDAS VISRAM AND COMPANY LIMITED		858030888	manufacture(51672-5330)

Revised: 3/2025 Taro Phamaceuticals U.S.A., Inc.