

HYDROCORTISONE WITH ALOE- hydrocortisone cream

Meijer Distribution 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.

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**

**DIST. BY MEIJER
DISTRIBUTION, INC.
2929 WALKER AVE NW
GRAND RAPIDS, MI 49544**

PRINCIPAL DISPLAY PANEL - 60 g Tube Carton

meijer™

Compare to Cortizone•10® active ingredient*

Maximum Strength

With Aloe

Anti-Itch Relief

1% Hydrocortisone Cream Antipruritic

NET WT 2 OZ (60 g)

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)				
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: 2KR89I4HIY)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-408-02	1 in 1 CARTON		
1		28.4 g in 1 TUBE		
2	NDC:41250-408-03	1 in 1 CARTON		
2		60 g in 1 TUBE		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL		part348	08/23/1995	

Labeler - Meijer Distribution Inc (006959555)

Registrant - Taro Pharmaceuticals U.S.A., Inc. (145186370)

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41250-408)