

## **HYDROCORTISONE PLUS- hydrocortisone cream**

**Walgreens**

*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.*

-----

### **MAXIMUM STRENGTH HYDROCORTISONE PLUS**

#### ***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, chamomile (anthemis nobilis) oil, citric acid, corn (zea mays) oil, glycerin, glyceryl stearate, isopropyl palmitate, maltodextrin, methylparaben, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

### **Questions or comments?**

1-800-WALGREENS (1-800-925-4733)

Distributed by: Walgreen Co.  
200 Wilmot Rd.  
Deerfield, IL 60015-4616

### **PRINCIPAL DISPLAY PANEL - 45g Tube Carton**

**Walgreens**

NDC 03630-063-06

**Compare to Cortizone-10<sup>®</sup>**

**Plus** active ingredient\*

*MAXIMUM STRENGTH*

***HYDROCORTISONE · PLUS***

*1% Hydrocortisone Anti-Itch Cream*

*NET WT 1.5 OZ (45g)*

*Anti-Itch Cream with Aloe*



## HYDROCORTISONE PLUS

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-0063
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	10 mg in 1 g

**Inactive Ingredients**

Ingredient Name	Strength
chamomile flower oil (UNII: 60F80Z61A9)	
citric acid monohydrate (UNII: 2968PHW8QP)	
corn oil (UNII: 8470G57WFM)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
isopropyl palmitate (UNII: 8CRQ2TH63M)	
maltodextrin (UNII: 7CVR7L4A2D)	
methylparaben (UNII: A218C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
stearyl alcohol (UNII: 2KR89I4HIY)	
vitamin A (UNII: 81G40H8B0T)	
cholecalciferol (UNII: 1C6V77QF41)	
alpha-tocopherol (UNII: H4N855PNZ1)	

**Product Characteristics**

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0063-06	1 in 1 CARTON		
1		45 g in 1 TUBE		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	06/01/2010	

**Labeler** - Walgreens (008965063)

## Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(0363-0063)

Revised: 2/2012

Walgreens