

## **RITE AID ANTI-ITCH- hydrocortisone cream**

### **Rite Aid Corporation**

*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.*

-----

### **Rite Aid®**

### **anti-itch**

### ***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 (anthesis 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?**

Call 1-866-923-4914

### **DISTRIBUTED BY:**

**RITE AID, 30 HUNTER LANE  
CAMP HILL, PA 17011**

### **PRINCIPAL DISPLAY PANEL - 60 g Tube Carton**

**RITE  
AID®  
PHARMACY**

**MAXIMUM STRENGTH**

**INTENSIVE HEALING FORMULA†**

**anti-itch cream**

relieves itch fast

temporary relief of: dry, itchy skin; eczema &

psoriasis; and inflammation, irritation & redness

calms, nourishes, hydrates

safe for sensitive skin

**1% hydrocortisone**

**with antioxidants & chamomile**

**†contains healing moisturizers enriched with vitamins A, D & E**

NET WT 2 OZ (60 g)



\*Compare to the active ingredient in Cortizone-10® Intensive Healing Formula

MAXIMUM STRENGTH

# anti-itch cream

1% hydrocortisone

with antioxidants & chamomile

## INTENSIVE HEALING FORMULA†

relieves itch fast

temporary relief of: dry, itchy skin; eczema & psoriasis; and inflammation, irritation & redness

calms, nourishes, hydrates

safe for sensitive skin

MAXIMUM STRENGTH

# anti-itch cream

1% hydrocortisone



MAXIMUM STRENGTH

# anti-itch cream

1% hydrocortisone

with antioxidants & chamomile

## INTENSIVE HEALING FORMULA†

relieves itch fast

temporary relief of: dry, itchy skin; eczema & psoriasis; and inflammation, irritation & redness

calms, nourishes, hydrates

safe for sensitive skin

NET WT 2 OZ (60 g)

†contains healing moisturizers enriched with vitamins A, D & E



### Questions? Call 1-866-923-4914

**Inactive ingredients** aloe barbadensis, cetylalcohol/sodium lauryl sulfate/sodium stearate, isopropyl palmitate, methylparaben, mineral oil, paraffin, petrolatum, cetylalcohol, chamomile (anthemide nobilis) oil, citric acid, com (sea may) oil, glycerin, glyceryl stearate, glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

• 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

### Other information

Drug Facts (continued)

This product is not manufactured or distributed by Johnson & Johnson, owner of the Cortizone-10® Intensive Healing Formula.

IF YOU'RE NOT SATISFIED, WE'LL HAPPILY REFUND YOUR MONEY. **GUARANTEE** RITE AID

**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.

## 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

Unless these results consult a doctor before or receive recommendation of a doctor

1% hydrocortisone

MAXIMUM STRENGTH  
anti-itch cream



DISTRIBUIDOR:  
RTE AID, 30 HUNTER LANE  
CAMP HILL, PA 17011  
MADE IN CANADA



MAXIMUM STRENGTH  
anti-itch cream

1% hydrocortisone

with antioxidants & chamomile

LPK-6689-1

1011-1

M132

T43

NO COPY /  
THIS FLAP  
AND EXP D





## RITE AID ANTI-ITCH

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:11822-2099
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>Hydrocortisone</b> (UNII: W14X0 X7BPJ) (Hydrocortisone - UNII:W14X0 X7BPJ)	Hydrocortisone	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>aloe vera whole</b> (UNII: KIZ4X2EHYX)	
<b>cetostearyl alcohol</b> (UNII: 2DMT128M1S)	
<b>sodium lauryl sulfate</b> (UNII: 368GB5141J)	
<b>sodium cetostearyl sulfate</b> (UNII: 7ZBS06BH4B)	
<b>chamomile flower oil</b> (UNII: 60F80 Z61A9)	
<b>citric acid monohydrate</b> (UNII: 2968PHW8QP)	
<b>corn oil</b> (UNII: 8470G57WFM)	
<b>glycerin</b> (UNII: PDC6A3C0OX)	
<b>glyceryl monostearate</b> (UNII: 230OU9XXE4)	
<b>isopropyl palmitate</b> (UNII: 8CRQ2TH63M)	
<b>maltodextrin</b> (UNII: 7CVR7L4A2D)	
<b>methylparaben</b> (UNII: A2I8C7HI9T)	
<b>mineral oil</b> (UNII: T5L8T28FGP)	
<b>paraffin</b> (UNII: I9O0E3H2ZE)	
<b>petrolatum</b> (UNII: 4T6H12BN9U)	
<b>propylene glycol</b> (UNII: 6DC9Q167V3)	
<b>propylparaben</b> (UNII: Z8IX2SC1OH)	
<b>water</b> (UNII: 059QF0KO0R)	
<b>stearyl alcohol</b> (UNII: 2KR89I4H1Y)	
<b>vitamin A palmitate</b> (UNII: 1D1K0N0VVC)	
<b>cholecalciferol</b> (UNII: 1C6V77QF41)	
<b>.alpha.-tocopherol acetate</b> (UNII: 9E8X80D2L0)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-2099-3	1 in 1 CARTON		
1		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** - Rite Aid Corporation (014578892)

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

### Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(11822-2099)

Revised: 1/2013

Rite Aid Corporation