

# **HYDROCORTISONE ACETATE ANTIPRURITIC (ANTI-ITCH)- hydrocortisone acetate cream**

**Sun Pharmaceutical Industries, Inc.**

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**Hydrocortisone 1% Cream**

## ***Drug Facts***

### **Active ingredient**

Hydrocortisone acetate (equivalent to 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**

cetostearyl alcohol, propylene glycol, purified water, sodium lauryl sulfate, white petrolatum

**Questions?**

Call 1-866-923-4914

Distributed by:

**Taro Pharmaceuticals**

**U.S.A., Inc.**

Hawthorne, NY 10532

**PRINCIPAL DISPLAY PANEL - 28.4 g Carton**

*Itch and Rash Relief*

**Hydrocortisone 1%**

**Cream**  
**Hydrocortisone Acetate**  
**Antipruritic (Anti-Itch)**  
**MAXIMUM STRENGTH**  
**NET WT 1 oz (28.4 g)**

MAXIMUM STRENGTH Compare to the active ingredient in Cortaid®\*

**Hydrocortisone 1%**  
**Cream**  
**Hydrocortisone Acetate**  
**Antipruritic (Anti-Itch)**  
*Itch and Rash Relief*



**Maximum Strength Relief of Itches and Rashes Due To:**

- Eczema • Psoriasis • Seborrheic Dermatitis • Poison Ivy, Oak, and Sumac
- Insect Bites • External Genital and Anal Itching • Soaps • Detergents
- Cosmetics • Jewelry

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*Itch and Rash Relief*  
**Hydrocortisone 1%**  
**Cream**  
**Hydrocortisone Acetate**  
**Antipruritic (Anti-Itch)**

MAXIMUM STRENGTH



NET WT 1 oz (28.4 g)

*Itch and Rash Relief*  
**Hydrocortisone 1%**  
 Cream  
 Hydrocortisone Acetate  
 Antipruritic (Anti-Itch)  
 NET WT 1 oz (28.4 g)

**Drug Facts (continued)**

**Other Information**

- To open, unseal, pull tab to remove foil seal, and screw cap back onto tube
- See caution or tube crimp for lot number and expiration date

**Inactive ingredients:** cetearyl alcohol, propylene glycol, purified water, sodium lauryl sulfate, white petrolatum

Questions? Call 1-866-923-1914



Made in Canada  
 U.S.A., Inc.  
 The OTC Pharmaceuticals  
 Distributed by:



**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
- Children under 12 years of age: consult a doctor

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

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

When using this product consult a doctor before exceeding recommended dosage

Ask a doctor before use if you have:

- a vaginal discharge • rectal bleeding • diaper rash

Do not use:

- in the eyes
- by putting the product into the rectum by using fingers or any mechanical device or applicator

**Warnings**

For external use only

- 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

**Uses**

Hydrocortisone acetate (equivalent to Hydrocortisone 1%):

**Active ingredient**

**Purpose**

Antipruritic (Anti-Itch) cream

**Drug Facts**

**Hydrocortisone 1%**  
 Cream  
 Hydrocortisone Acetate

Antipruritic (Anti-Itch)  
 MAXIMUM STRENGTH  
*Itch and Rash Relief*

This product is not intended for internal or external use. Read the label and follow directions. ©2010 OTC Pharmaceuticals, Inc. All rights reserved.

# HYDROCORTISONE ACETATE ANTIPRURITIC (ANTI-ITCH)

hydrocortisone acetate cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51672-2069
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>HYDROCORTISONE ACETATE</b> (UNII: 3X7931PO74) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE ACETATE	1 g in 100 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CETOSTEARYL ALCOHOL</b> (UNII: 2DMT128M1S)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:51672-2069-2	1 in 1 CARTON	06/01/2001	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2069-9	454 g in 1 JAR; Type 0: Not a Combination Product	06/01/2001	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC Monograph Drug	M017	06/01/2001	

**Labeler** - Sun Pharmaceutical Industries, Inc. (146974886)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Sun Pharma Canada Inc.		243339023	manufacture(51672-2069)