

## **SHOPKO HYDROCORTISONE- hydrocortisone ointment**

**Shopko Stores Operating Co., LLC**

*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.*

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**Shopko®**

**Hydrocortisone**

***Drug Facts***

### **Active ingredient**

Hydrocortisone 1%

### **Purpose**

Anti-itch

### **Uses**

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

- 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**

fractionated coconut oil, methylparaben, propylparaben, white petrolatum

### **Questions?**

Call 1-866-923-4914

**PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton**

**NDC 37012-018-02**

**SHOPKO®**

Maximum Strength

**Hydrocortisone Ointment 1%**

**Antipruritic (Anti-Itch)**

Itch & Rash Relief

NET WT 1 oz (28.4 g)

SHOPKO®

Compare to the active ingredient  
in Cortizone•10®\*

Maximum Strength

# Hydrocortisone Ointment 1%

Antipruritic (Anti-Itch)

Itch & Rash Relief

- Skin Irritation & Rashes • Inflammation & Redness
- Insect Bites, Poison Ivy

LK-7516-0  
0314-0  
M693

SHOPKO®

Maximum Strength

# Hydrocortisone Ointment 1%

Antipruritic (Anti-Itch)

Itch & Rash Relief

NDC 37012-018-02

NET WT. 1 oz (28.4 g)

SHOPKO®  
Maximum Strength  
**Hydrocortisone  
Ointment 1%**  
Antipruritic (Anti-Itch)  
Itch & Rash Relief

T28



Manufactured for Shopko  
By Taro Pharmaceuticals Inc.  
Brampton, Ontario, Canada L6T 1C1  
1-866-923-4914  
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Operating Co., LLC  
Made in Canada



By Refund Or Exchange

NO COPY ON THIS FLAP  
FOR LOT # AND EXPIRY  
DATE PRINT ONLY

<b>Drug Facts</b>	
<b>Active Ingredient</b> Hydrocortisone 1% Ant-Itch	
<b>Purpose</b> Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.	
<b>Drug Facts (continued)</b>	
<b>Directions</b> • 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, adult use • 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	<b>Warnings</b> 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
<b>Other Information</b> • To open: unscrew cap, pull tab to remove foil seal, and screw cap back onto tube • see carton or tube crimp for lot number and expiration date • store at room temperature • see carton or tube crimp for lot number and expiration date	<b>Questions? Call 1-866-923-4914</b> *This product is not manufactured or distributed by Chatham, Inc., owner of the registered trademark Cortizone•10®.
<b>Inactive Ingredients</b> fractionated coconut oil, methylparaben, p-cytoparaben, white petrolatum	

SHOPKO®

SHOPKO HYDROCORTISONE  
hydrocortisone ointment

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:370 12-0 18
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

<b>Ingredient Name</b>	<b>Strength</b>
<b>Medium-chain triglycerides</b> (UNII: C9H2L21V7U)	
<b>Methylparaben</b> (UNII: A218C7H9T)	
<b>Propylparaben</b> (UNII: Z8IX2SC1OH)	
<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:370 12-0 18-02	1 in 1 CARTON		
1		28.4 g in 1 TUBE		

**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 NOT FINAL	part348	10/03/1989	

**Labeler** - Shopko Stores Operating Co., LLC (023252638)**Registrant** - Taro Pharmaceuticals U.S.A., Inc. (145186370)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(370 12-0 18)

Revised: 5/2014

Shopko Stores Operating Co., LLC