

SHOPKO HYDROCORTISONE INTENSIVE HEALING FORMULA- hydrocortisone cream
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.

Shopko® Hydrocortisone Cream 1% Intensive Healing Formula

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**

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

SHOPKO®

NDC 37012-099-02

Maximum Strength

Hydrocortisone Cream 1%

Antipruritic (Anti-Itch)

Intensive Healing Formula[†]

NET WT 1 OZ (28.4 g)

SHOPKO®

Maximum Strength

Hydrocortisone Cream 1%

Antipruritic (Anti-Itch)

Intensive Healing Formula†

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

†Contains Healing Moisturizers Enriched With Vitamins A, D & E
With Antioxidants & Chamomile

Maximum Strength Relief of:

- Dry, Itchy Skin • Eczema & Psoriasis • Inflammation, Irritation & Redness

SHOPKO®

Maximum Strength

Hydrocortisone Cream 1%

Antipruritic (Anti-Itch)

Intensive Healing Formula†

NDC 37012-099-02


NET WT 1 OZ (28.4 g)

Questions? Call 1-866-923-4914

Inactive ingredients also barbadensis, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, chamomile (anthemisis nobilis) oil, citric acid, com (sea rays) oil, glycerin, glyceryl stearate, isopropyl palmitate, maledoxethin, methylparaben, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

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

Drug Facts (continued)



001801977824

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

SHOPKO®
Satisfaction
Guaranteed

By Refund Or Exchange

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 uses of this product should be only under the advice and supervision of a doctor

SHOPKO®

Drug Facts

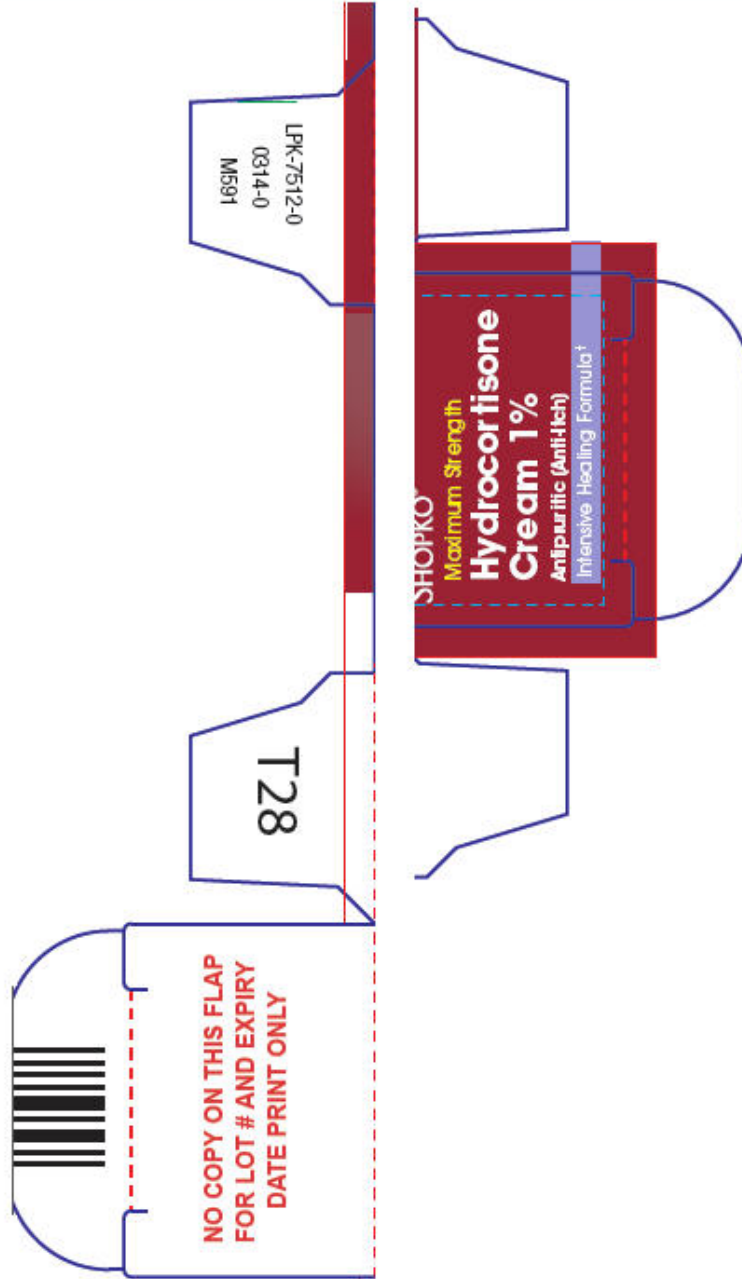
Active ingredient
Hydrocortisone 1%

Uses

- temporary relief of itching associated with minor skin irritations and rashes due to insect bites • poison ivy, poison oak, or poison sumac • soaps • detergents • cosmetics
- eczema • seborrheic dermatitis • psoriasis • external genital and anal itching
- jewelry

Purpose
Anti-itch cream

* This product is not manufactured or distributed by Chattem, Inc. • Intensive Healing Formula • 10g



SHOPKO HYDROCORTISONE INTENSIVE HEALING FORMULA

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-099
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: WI4X0X7BPJ) (Hydrocortisone - UNII:WI4X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
aloe vera whole (UNII: KIZ4X2EHYX)	
cetostearyl alcohol (UNII: 2DMT128M1S)	
sodium lauryl sulfate (UNII: 368GB5141J)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
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: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6HI2BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0KO0R)	
stearyl alcohol (UNII: 2KR89I4HIY)	
Vitamin A palmitate (UNII: 1D1K0N0VVC)	
cholecalciferol (UNII: 1C6V77QF41)	
.alpha.-tocopherol acetate (UNII: 9E8X80D2L0)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-099-02	1 in 1 CARTON		
1		28.4 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 - Shopko Stores Operating Co., LLC (023252638)**Registrant** - Taro Pharmaceuticals U.S. A., Inc. (145186370)

Establishment			
Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(37012-099)

Revised: 4/2014

Shopko Stores Operating Co., LLC