

SHOPKO MAXIMUM STRENGTH- 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®

Maximum Strength

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

aloe powder, cetearyl alcohol/sodium lauryl sulfate/sodium cetearyl sulfate, citric acid, glycerin, glyceryl monostearate, methylparaben, mineral oil, paraffin wax, propylparaben, purified water, sodium lauryl sulfate, stearyl alcohol

Questions?

Call **1-866-923-4914**

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

NDC 37012-408-02

SHOPKO®

Maximum Strength

Hydrocortisone Cream 1%

Antipruritic (Anti-Itch)

Itch & Rash Relief with Aloe

NET WT 1 OZ. (28.4 g)

SHOPKO®

Compare to the active ingredient
in Cortizone•10®*

Maximum Strength

Hydrocortisone Cream 1%

Antipruritic (Anti-Itch)

Itch & Rash Relief with Aloe

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

LK-75-14-1
05-14-1
M592

SHOPKO®

Maximum Strength

Hydrocortisone Cream 1%

Antipruritic (Anti-Itch)

Itch & Rash Relief with Aloe

NDC 370-12-408-02

NET WT. 1 OZ. (28.4 g)

SHOPKO®
Maximum Strength
Hydrocortisone
Cream 1%
Antipruritic (Anti-Itch)
Itch & Rash Relief with Aloe

T28



Manufactured for Shopko
By Taro Pharmaceuticals Inc.
Brampton, Ontario, Canada L6T 1C1
1-888-923-4914
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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



Drug Facts

Active Ingredient
Hydrocortisone 1%
Anti-Itch

Purpose
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
• For itching and skin irritation, inflammation, and redness:
• 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
• when practical, clean the affected area with mild soap and warm water and rinse thoroughly
• gently dry by patting or blotting with 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

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 if
• rectal bleeding occurs

Questions? Call 1-888-923-4914
*This product is not manufactured or distributed by Chatterm, Inc., owner of the registered trademark Cortizone 10®.

Inactive Ingredients also powder, cetylalcohol, sodium lauryl sulfate, mineral oil, paraffin wax, propylparaben, purified water, sodium methacrylate, cetyl alcohol, glycerin, glyceryl monostearate, methylparaben, mineral oil, paraffin wax, propylparaben, purified water, sodium lauryl sulfate, stearyl alcohol

SHOPKO®

SHOPKO MAXIMUM STRENGTH

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:370 12-408
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
cetostearyl alcohol (UNII: 2DMT128M1S)	
sodium lauryl sulfate (UNII: 368GB5141J)	
SODIUM CETOSTEARYL SULFATE (UNII: 7ZBS06BH4B)	
citric acid monohydrate (UNII: 2968PHW8QP)	
glycerin (UNII: PDC6A3C0OX)	
glyceryl monostearate (UNII: 230OU9XXE4)	
methylparaben (UNII: A2I8C7HI9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K0OR)	
stearyl alcohol (UNII: 2KR89I4HIY)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:37012-408-02	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(37012-408)