

**WESTERN FAMILY HYDROCORTISONE PLUS 12 MOISTURIZERS- hydrocortisone cream**  
**Western Family Foods Inc**

*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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**Western Family®**  
**HydroCortisone Plus 12 Moisturizers**

***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 (anthemis 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:

**Western Family Foods, Inc.**

P.O. Box 4057, Portland, OR 97208

### **PRINCIPAL DISPLAY PANEL - 28 g Tube Carton**

***HydroCortisone***

***1% Hydrocortisone Anti-Itch CREAM PLUS***

***12 MOISTURIZERS***

NET WT 1 OZ (28g)

***MAXIMUM STRENGTH***



COMPARE TO THE ACTIVE  
INGREDIENT OF CORTIZONE 10® PLUS\*

**ITCH RELIEF**  
**PLUS 12 SOOTHING**  
**MOISTURIZERS**

**MAXIMUM STRENGTH**

Relieves Skin Irritations, Enriched with  
Vitamins A & D and Soothing Aloe

**HydroCortisone**  
1% Hydrocortisone Anti-Itch **CREAM PLUS**  
**12 MOISTURIZERS**

NET WT 1 OZ (28g)

**MAXIMUM STRENGTH**



LPK-3443-3  
0509-3  
M496

T 28

**Drug Facts** (continued)  
**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 cap for lot number and expiration date  
**Inactive ingredients** • active ingredients: 1% hydrocortisone, cetaryl alcohol, sodium lauryl sulfate, cetaryl alcohol, glycerin, glyceryl stearate, copolymer, parabens, methylparaben, ethanol, perfume, polyethylene glycol, propylparaben, purified water, stannyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).  
**Questions?** Call 1-866-923-4914



**Drug Facts**  
**Active ingredient** Hydrocortisone 1%  
**Uses** • temporary relief of itching associated with mild or skin irritations and rashes due to • eczema • insect bites • poison ivy, poison oak, or poison sumac • sores • dermatitis • hemorrhoids • 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 eye  
• by putting the product into the rectum by using fingers or any mechanical device or applicator  
**Ask a doctor before use if you have** • genital 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 does not improve 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 areas 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  
**Purpose** Anti-itch cream

\*This product is not  
distributed by Pfizer  
Consumer Healthcare,  
owner of the  
registered trademark  
Cortizone-10® Plus.  
 Proudly Distributed By  
Western Family Foods, Inc.  
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**WESTERN FAMILY HYDROCORTISONE PLUS 12 MOISTURIZERS**

hydrocortisone cream

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:55312-063

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
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: 4T6H12BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
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:55312-063-02	1 in 1 CARTON		
1		28 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part348	10/03/1989	

Labeler - Western Family Foods Inc (192166072)

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

## Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(55312-063)

Revised: 3/2013

Western Family Foods Inc