# KAISER PERMANENTE HYDROCORTISONE- hydrocortisone acetate cream Kaiser Foundation Hospitals

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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# KAISER PERMANENTE $_{\mathbb{R}}$ Hydrocortisone

**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** 

Manufactured by

Taro Pharmaceuticals Inc.

Brampton, Ontario, Canada L6T 1C1

Distributed by

**Kaiser Foundation Hospitals** 

Livermore, CA 94551-9756

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

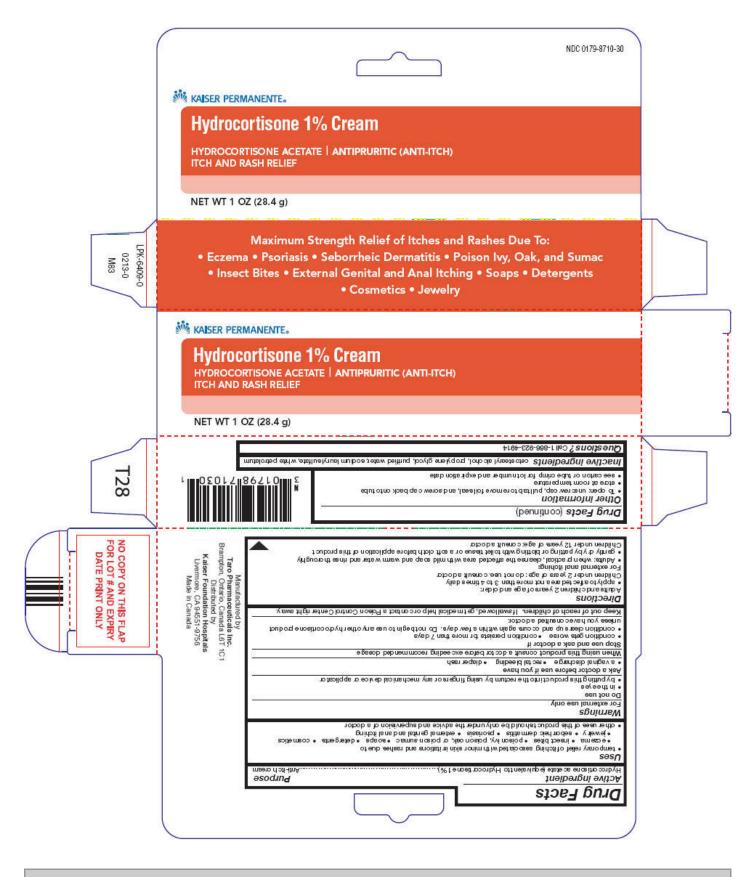
KAISER PERMANENTE®

Hydrocortisone 1% Cream

HYDROCORTISONE ACETATE | ANTIPRURITIC (ANTI-ITCH)

ITCH AND RASH RELIEF

NET WT 1 OZ (28.4 g)



#### KAISER PERMANENTE HYDROCORTISONE

hydrocortisone acetate cream

#### **Product Information**

Product Type

HUMAN OTC DRUG LABEL

Item Code (Source)

NDC:0179-8710

Route of Administration	TOPICAL	DEA Schedule

### **Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
Hydrocortisone acetate (Hydrocortisone)	Hydrocortisone acetate	1 g in 100 g

Inactive Ingredients	
Ingredient Name	Strength
CETOSTEARYL ALCOHOL	
PROPYLENE GLYCOL	
WATER	
SODIUM LAURYL SULFATE	
PETROLATUM	

Product Characteristics			
Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

P	Packaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0179-8710-30	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	06/01/2001	

# Labeler - Kaiser Foundation Hospitals (053052619)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(0179-8710)	

Revised: 3/2013 Kaiser Foundation Hospitals