HYDROCORTISONE ACETATE ANTIPRURITIC (ANTI-ITCH)- hydrocortisone acetate cream
Taro Pharmaceuticals U.S.A., 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.

Hydrocortisone 1% Cream

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

Distributed by:
Taro Pharmaceuticals
U.S.A., Inc.
Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 28.4 g Carton

Itch and Rash Relief

Hydrocortisone 1%
Cream
Hydrocortisone Acetate
Antipruritic (Anti-Itch)

MAXIMUM STRENGTH

NET WT 1 oz (28.4 g)

HYDROCORTISONE ACETATE ANTIPRURITIC (ANTI-ITCH)

hydrocortisone acetate cream

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51672-2069
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hydrocortisone Acetate (UNII: 3X7931PO74) (Hydrocortisone - UNII:W4X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
cetostearyl alcohol (UNII: 2DMT128M1S)	
propylene glycol (UNII: 6DC9Q167V3)	
water (UNII: 059QF0KO0R)	
sodium lauryl sulfate (UNII: 368GB5141J)	
petrolatum (UNII: 4T6H12BN9U)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51672-2069-2	1 in 1 CARTON	06/01/2001	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:51672-2069-9	454 g in 1 JAR; Type 0: Not a Combination Product	06/01/2001	

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
OTC MONOGRAPH NOT FINAL	part348	06/01/2001	

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

Establishment			
Name	**Address**	**ID/FEI**	**Business Operations**
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(51672-2069)

Revised: 3/2023 Taro Pharmaceuticals U.S.A., Inc.