MEIJER ITCH AND RASH RELIEF- hydrocortisone ointment Meijer Distribution 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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Itch & Rash Relief

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch ointment

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

Fractionated Coconut Oil, Methylparaben, Propylparaben, White Petrolatum

Questions?

Call 1-866-923-4914

DIST. BY MEIJER DISTRIBUTION, INC. 2929 WALKER AVE NW GRAND RAPIDS, MI 49544

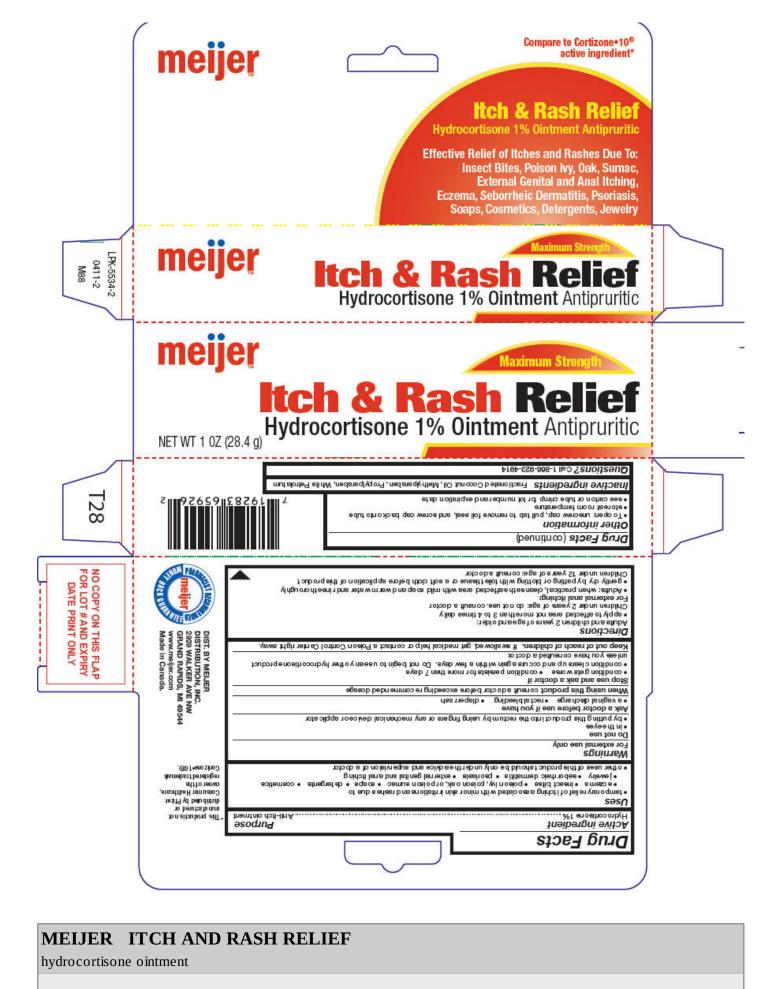
PRINCIPAL DISPLAY PANEL - 28.4 Tube Carton

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Maximum Strength

Itch & Rash Relief
Hydrocortisone 1% Ointment Antipruritic

NET WT 10Z (28.4 g)



Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41250-018	
Route of Administration	TOPICAL			

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Hydrocortisone (UNII: WI4X0 X7BPJ) (Hydrocortisone - UNII:WI4X0 X7BPJ)	Hydro c o rtis o ne	1 g in 100 g	

Inactive Ingredients			
Ingredient Name	Strength		
Medium-chain triglycerides (UNII: C9H2L21V7U)			
Methylparaben (UNII: A2I8C7HI9T)			
Propylparaben (UNII: Z8IX2SC1OH)			
Petrolatum (UNII: 4T6H12BN9U)			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41250-018-02	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	10/03/1989		

Labeler - Meijer Distribution Inc (006959555)

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

Establishment				
Name	Address	ID/FEI	Business Operations	
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(41250-018)	

Revised: 2/2013 Meijer Distribution Inc