SUNMARK HYDROCORTISONE- hydrocortisone ointment
McKesson

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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sunmark™
Hydrocortisone

Drug Facts

Active ingredient

Hydrocortisone 1%

Purpose

Anti-itch

Uses

for the temporary relief of itching associated with minor skin irritations, inflammation and rashes due to:

- eczema
- seborrheic dermatitis
- psoriasis
- insect bites
- poison ivy, oak, sumac
- soaps
- detergents
- cosmetics
- jewelry
- 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**
- **avoid contact with the eyes**
- **do not put this product into the rectum by using fingers or any mechanical device or applicator**

Stop using this product and ask a doctor

- in case of bleeding
- if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days
- before you begin using any other hydrocortisone product

Do not use this product and ask a doctor

- if you have a vaginal discharge
- before treating diaper rash
- before using on children under 2 years of age

For External Anal Itching Users

- do not exceed the recommended daily dosage unless directed by a doctor
- in case of bleeding, consult a doctor promptly
- do not put this product into the rectum by using fingers or any mechanical device or applicator
- children under 12 years of age: consult a doctor

Keep out of the reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Before using any medication, read all label directions. Keep this carton. It contains important information.

Directions

- 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
- adults and children 12 years of age and older: apply to the affected area not more than 3 to 4 times daily
- children under 12 years of age: Do not use, consult a doctor

Other information

- to open: unscrew cap and pull tab to remove foil seal
- if seal has been broken, do not use this product. Return product to the store where you bought it
- store at controlled room temperature 15° – 30°C (59°- 86°F)
- see carton or tube crimp for lot number and expiration date

Inactive ingredients

fractionated coconut oil, methylparaben, propylparaben, white petrolatum

Distributed by McKesson
One Post Street
San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

sunmark™

hydrocortisone ointment 1%

Antipruritic (Anti-Itch)

MAXIMUM STRENGTH

NET WT 1 OZ (28.4 g)

sunmark™

COMPARE TO CORTIZONE•10® ACTIVE INGREDIENT*

NDC 49348-522-72

Effective itch & rash relief for eczema, psoriasis, seborrheic dermatitis

MAXIMUM STRENGTH

Effective relief of itches & rashes due to:

- Eczema • Seborrheic Dermatitis • Psoriasis
- Insect Bites • Poison Ivy • Poison Oak • Poison Sumac
- External Genital and Anal Itching
- Soaps • Cosmetics • Detergents • Jewelry

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Another Quality Product
Distributed by McKesson
One Post Street
San Francisco, CA 94104
Money Back Guarantee
Please visit us at
www.sunmarkbrand.com

MCKESSON
Empowering Healthcare

Made in Canada.

*** This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Cortizone•10®.**

Drug Facts (continued)

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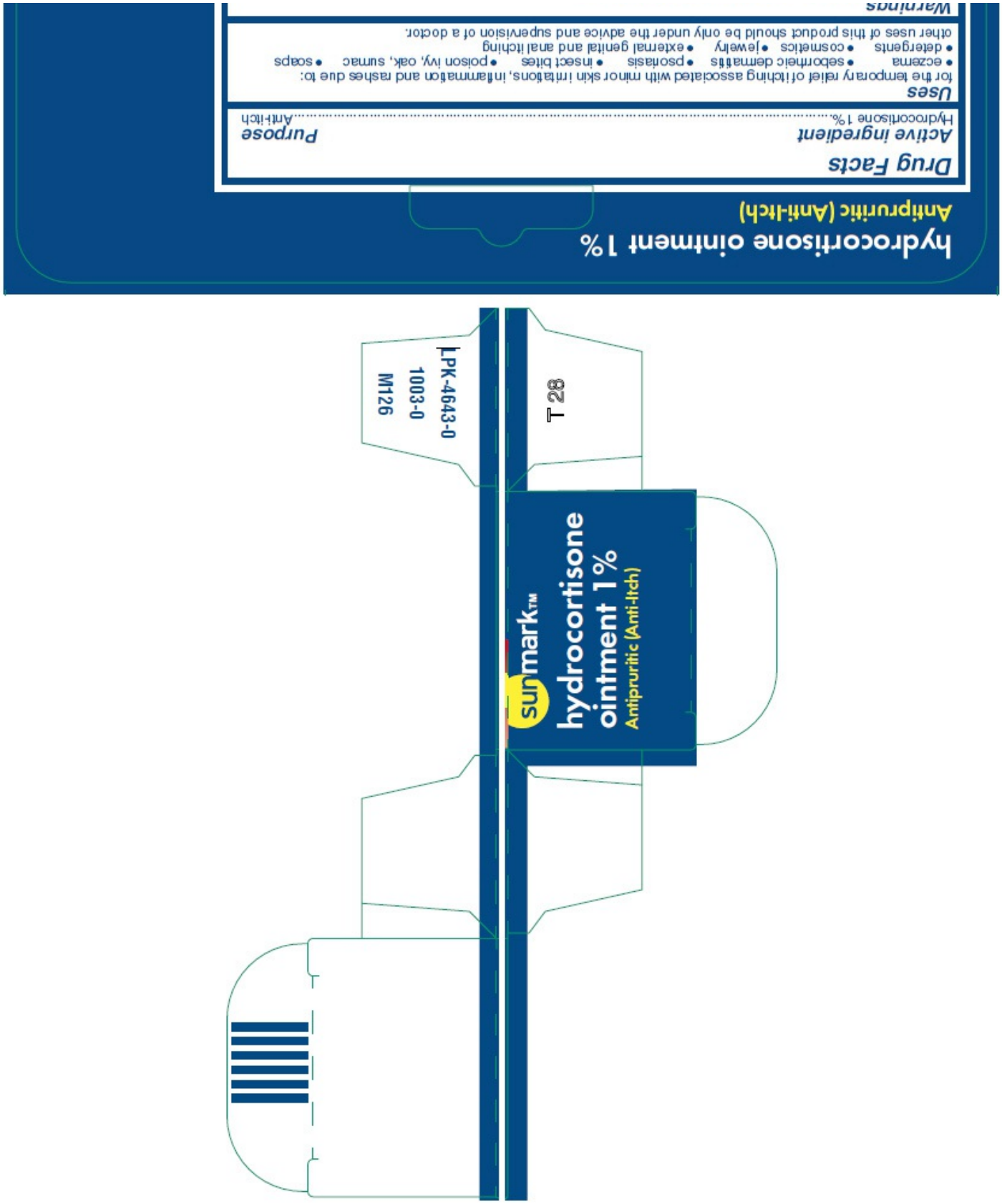

SUNMARK HYDROCORTISONE

hydrocortisone ointment

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-522
Route of Administration	TOPICAL	DEA Schedule	

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
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:49348-522-72	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 - McKesson (177667227)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(49348-522)