

SUNMARK HYDROCORTISONE PLUS- hydrocortisone cream
Strategic Sourcing Services LLC

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.

sunmark™
Hydrocortisone Plus 12 Moisturizers

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**

Stop using this product and ask a doctor

- 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 this and all drugs 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 direction. Keep this carton. It contains important information.

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, ask a doctor

For External Anal Itching Users

- 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

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

Inactive ingredients

aloe barbadensis, cetearyl alcohol, 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, sodium cetearyl sulfate, sodium lauryl sulfate, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

Distributed by McKesson
One Post Street
San Francisco, CA 94104

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

sunmark™

hydrocortisone cream 1%

Antipruritic (Anti-Itch)

MAXIMUM STRENGTH PLUS 12 MOISTURIZERS

NET WT 1 OZ (28.4 g)

sunmark™

COMPARE TO CORTIZONE•10® PLUS ACTIVE INGREDIENT*

NDC 49348-441-72

Enriched with vitamins A, D & E

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

MAXIMUM STRENGTH PLUS 12 MOISTURIZERS

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

sunmark™

hydrocortisone cream 1%

Antipruritic (Anti-Itch)

MAXIMUM STRENGTH PLUS 12 MOISTURIZERS

NET WT 1 OZ (28.4 g)

Inactive ingredients: aloe barbadensis, cetaryl alcohol, chamomile (anthemisis nobilis) oil, citric acid, com (zea mays) oil, glycerin, stearate, isopropyl palmitate, methylparaben, mineral oil, paraffin, petrolatum, propylene glycol, propylparaben, purified water, sodium cetaryl sulfate, sodium lauryl sulfate, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).



Other information ■ unscrew cap, pull tab to remove foil seal, and screw cap back onto tube ■ if seal has been broken, do not use this product. Return product to the store where you bought it. ■ store at controlled room temperature 59°-86°F ■ see carton or tube clamp for lot number and expiration date

Drug Facts (continued)

For External Anal Itching Users ■ 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

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, ask a doctor

Before using any medication, read all label directions. Keep this carton. It contains important information. If swallowed, get medical help or contact a Poison Control Center right away.

Keep this and all drugs out of the reach of children.

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

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

Do not use this product and ask a doctor ■ if you have a vaginal discharge ■ before treating diaper rash ■ before you begin using any other hydrocortisone product ■ if condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days

Stop using this product and ask a doctor

■ for external use only ■ avoid contact with the eyes

Made in Canada.

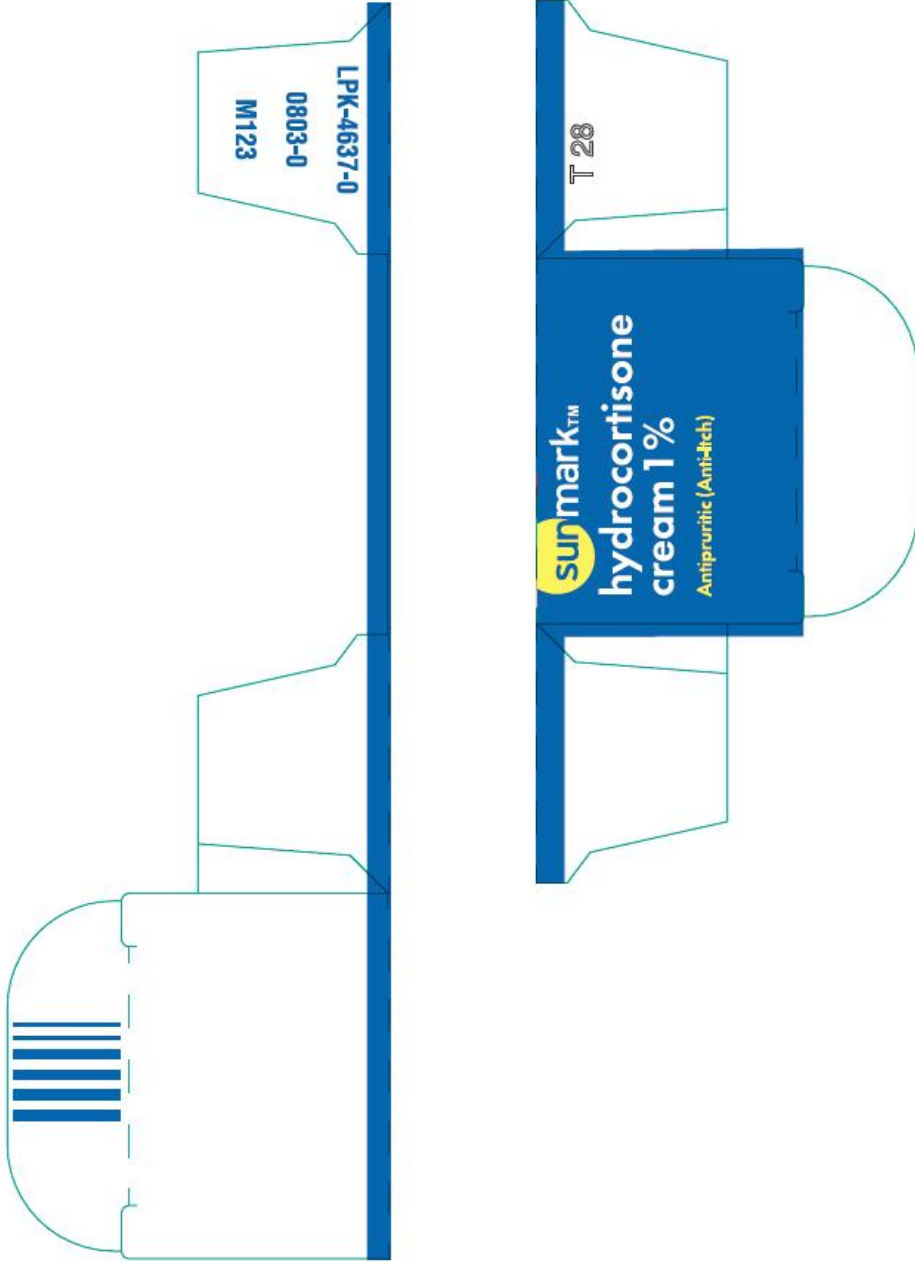
Another Quality Product Distributed by McKesson One Post Street San Francisco, CA 94104 Money Back Guarantee Please visit us at www.sunmarkbrand.com

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McKesson

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hydrocortisone cream 1%

Antipruritic (Anti-Itch)



Drug Facts
Hydrocortisone 1%
Active ingredient

Purpose Ant-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.

Warnings
other uses of this product should be only under the advice and supervision of a doctor.

hydrocortisone cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-441
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Hydrocortisone (UNII: W14X0X7BPJ) (Hydrocortisone - UNII:W14X0X7BPJ)	Hydrocortisone	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
cetostearyl alcohol (UNII: 2DMT128M1S)	
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: 4T6HI2BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
sodium lauryl sulfate (UNII: 368GB5141J)	
stearyl alcohol (UNII: 2KR89I4H1Y)	
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:49348-441-72	1 in 1 CARTON	10/03/1989	
1		28.4 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

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

