

HYDROCORTISONE PLUS 12 MOISTURIZERS- hydrocortisone 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 Plus 12 Moisturizers

Drug Facts

Active ingredient

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

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

Questions?

Call 1-866-923-4914

Distributed by:

Taro Pharmaceuticals U.S.A., Inc.

Hawthorne, NY 10532

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Itch and Rash Relief

MAXIMUM STRENGTH

Hydrocortisone 1%

Cream

Antipruritic (Anti-Itch)

Plus

12 Moisturizers

NET WT 1 oz (28.4 g)

Compare to the active ingredient in Cortizone-10® Plus*

MAXIMUM STRENGTH

Hydrocortisone 1% Cream

Antipruritic (Anti-Itch)

Itch and Rash Relief



Enriched With Vitamins A, D & E

LPK-3286-3
1108-3
M234

Maximum Strength Relief of Itches and Rashes Due To:

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

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Itch and Rash Relief

MAXIMUM STRENGTH

Hydrocortisone 1% Cream

Antipruritic (Anti-Itch)



NET WT 1 oz (28.4 g)

Itch and Rash Relief
Hydrocortisone 1%
Cream
Antipruritic (Anti-Itch)

NET WT 1 oz (28.4 g)

NET WT 1 oz (28.4 g)

Questions? Call 1-866-923-4914

Inactive ingredients also barbed arsis, cebra/lyalcohol/iodium laurylsulfate/sodium cocoyl/sulfate, chamomile/anthemisis nobilifol, citric acid, corn (zea mays) oil, glycerin, glyceryl searate, iso propyl palmitate, maledoxtrin, methylparaben, mineral oil, petrolatum, propylene glycol, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate).

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 for comp for lot number and expiration date.

Drug Facts (continued)

TARO

Distributed by:
Taro Pharmaceuticals
U.S.A., Inc.
Hawthorne, NY 10822
Made in Canada.

Uses temporary relief of itching associated with minor skin irritation and rashes due to • eczema • insect bites • poison oak, or poison sumac • soaps • detergents • cosmetics • jewelry • seborrheic dermatitis • perianitis • 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 a medical 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 does not improve or occurs again within a few days. Do not begin to use any other hydrocortisone product unless you have consulted 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, consult a doctor.

For external anal itching: • Adults: with an product, cleanse the affected area with mild soap and warm water and dry 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.

HYDROCORTISONE PLUS 12 MOISTURIZERS			
hydrocortisone cream			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51672-2063
Route of Administration	TOPICAL		

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
cetostearyl alcohol (UNII: 2DMT128M1S)	
sodium lauryl sulfate (UNII: 368GB5141J)	
sodium cetostearyl sulfate (UNII: 7ZBS06BH4B)	
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: A218C7H9T)	
mineral oil (UNII: T5L8T28FGP)	
paraffin (UNII: I9O0E3H2ZE)	
petrolatum (UNII: 4T6H12BN9U)	
propylene glycol (UNII: 6DC9Q167V3)	
propylparaben (UNII: Z8IX2SC1OH)	
water (UNII: 059QF0K00R)	
stearyl alcohol (UNII: 2KR89I4HIY)	
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:51672-2063-2	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	

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

Name	Address	ID/FEI	Business Operations
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Revised: 1/2020

Taro Pharmaceuticals U.S.A., Inc.