

SAFeway HYDROCORTISONE PLUS 12 MOISTURIZERS- hydrocortisone cream
Safeway 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.

SAFeway™
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)

DISTRIBUTED BY SAFEWAY INC.

P.O. BOX 99

PLEASANTON, CA 94566-0009

1-888-SAFEWAY

PRINCIPAL DISPLAY PANEL - 28.4 g Tube Carton

Maximum Strength

NDC 21130-063-02

**Compare to the active
ingredient in Cortizone**

•10[®] Plus[®] and Cortaid[®]

Intensive Therapy*

Hydrocortisone 1% Cream Plus 12 Moisturizers

Antipruritic (Anti-Itch)

• Itch and Rash Relief • Enriched With Vitamins A, D & E

NET WT 1 OZ (28.4 g)

SAFEWAY[™]

Maximum Strength

Hydrocortisone 1% Cream Plus 12 Moisturizers

Antipruritic (Anti-Itch)

• Itch and Rash Relief • Enriched With Vitamins A, D & E

NDC 21130-063-02
Compare to the active
ingredient in Cortizone
•10⁺ Plus and Cortaid[®]
Intensive Therapy*

NET WT 1 OZ (28.4g)

SAFEMAY 

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

T 28

LPK-5811-1
0509-1
M574

Maximum Strength

Hydrocortisone 1% Cream Plus 12 Moisturizers

Antipruritic (Anti-Itch)

• Itch and Rash Relief • Enriched With Vitamins A, D & E

NDC 21130-063-02
Compare to the active
ingredient in Cortizone
•10⁺ Plus and Cortaid[®]
Intensive Therapy*

NET WT 1 OZ (28.4g)

SAFEMAY 

Maximum Strength
Hydrocortisone 1%
Cream Plus 12 Moisturizers
Antipruritic (Anti-Itch)

Drug Facts (continued)

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 also barbendens, octearyl alcohol/sodium lauryl sulfate/sodium octearyl sulfate, chamomile (anthemris nobilis) oil, citric acid, corn (zea mays) oil, glycerin, glyceryl stearate, isopropyl palmitate, methylparaben, mineral oil, paraffin, polybutene-1, propylparaben, purified water, stearyl alcohol, vitamin A (retinyl palmitate), vitamin D (cholecalciferol), vitamin E (tocopheryl acetate)

Drug Facts

Active ingredient
Hydrocortisone 1%
Purpose
Antipruritic (Anti-Itch) and Rash Relief

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
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
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away, 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: 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.

DISTRIBUTED BY SAFEMAY INC.
P.O. BOX 99
PLEASANTON, CA 94586-0099
1-888-SAFEMAY
www.safemay.com
MADE IN CANADA
52640



*This product is not
distributed by Pfizer
Consumer Healthcare,
distributors of
Cortizone-10 Plus
or Johnson & Johnson,
distributors of
Cortaid[®] Intensive Therapy.

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:21130-063
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: 2DMT128MIS)	
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)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
METHYL PARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (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:21130-063-02	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 - Safeway Inc. (009137209)

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

Establishment

Name	Address	ID/FEI	Business Operations
Taro Pharmaceuticals Inc.		206263295	MANUFACTURE(21130-063)

Revised: 3/2013

Safeway Inc.