

CLINICALM- hydrocortisone cream
CP Skin Health Group, 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.

CliniCalm® 1% Hydrocortisone Cream

Drug Facts

Active ingredient

Hydrocortisone (1%)

Purpose

Antipruritic (anti-itch)

Uses

For the temporary relief of itching and discomfort associated with minor skin irritations and rashes due to eczema, psoriasis, insect bites, poison ivy, poison oak, or poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, etc.

Warnings

For external use only

Avoid contact with the eyes.

If condition worsens, or if symptoms persist for more than 7 days or clear up and occur again within a few days, stop use of this product and do not begin use of any other hydrocortisone product unless you have consulted a physician.

Do not use for the treatment of diaper rash. Consult a physician.

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. If product is 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 physician.

Other information

Store at 15°–25°C (59°–77°F).

Inactive ingredients

Water/Aqua/Eau, Glycerin, Caprylic/Capric Triglyceride, Alcohol Denat., Cetearyl Olivatate, Squalane, Olea Europaea (Olive) Fruit Oil, Sorbitan Olivatate, Caprylyl Glycol, Phenoxyethanol, Pentylene Glycol, Linum Usitatissimum (Linseed) Seed Oil, Xanthan Gum, 4-t-Butylcyclohexanol, 1,2-Hexanediol, Honey/Mel/Miel, Carbomer, Phospholipids, Asiaticoside, Beta-Glucan, Bisabolol, Lysine HCl, Sodium Hydroxide, Aloe Barbadensis Leaf Juice Powder, Ceramide NP, Sorbic Acid, Trisodium Ethylenediamine Disuccinate, Helianthus Annuus (Sunflower) Seed Oil, Butylene Glycol, Hyaluronic Acid, Sphingolipids, Tocopherol, Tropolone, Hydroxyphenyl Propamidobenzoic Acid.

Questions or comments?

877.722.7546

PRINCIPAL DISPLAY PANEL - 60 g Tube Box

PCA skin ®

CliniCalm ® 1%

2.1 oz/60g

PCA skin®

Drug Facts

Active ingredient	Purpose
Hydrocortisone 1%	Anti-itch (anti-Itch)

Uses
• for the temporary relief of itching associated with minor skin irritations and rashes due to eczema, psoriasis, insect bites, poison ivy, poison oak, or poison sumac, soaps, detergents, cosmetics, jewelry, seborrheic dermatitis, etc. • other uses of this product should be only under the advice and supervision of a physician.

Warnings
For external use only.
When using this product: • avoid contact with the eyes.
Stop use 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, discontinue use of this product and consult a physician.
Do not use for the treatment of diaper rash. Consult a physician.
Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

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Manufactured for CP Skin Health Group, Inc.
Scottsdale, AZ 85251, USA

Drug Facts (continued)

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 physician.

Other information
• store at 15°-25°C (59°-77°F)

Inactive ingredients
Water, Glycerin, Caprylic/Capric Triglyceride, Petrolatum, Stearic Acid, Stearalkonium Chloride, Hydroxyethyl Acrylate, Carbomer, Xanthan Gum, Hydroxyethyl Methacrylate, Polyethylene Glycol, Polysorbate 20, Polysorbate 80, Polysorbate 40, Polysorbate 60, Polysorbate 120, Polysorbate 150, Polysorbate 180, Polysorbate 200, Polysorbate 210, Polysorbate 220, Polysorbate 230, Polysorbate 240, Polysorbate 250, Polysorbate 260, Polysorbate 270, Polysorbate 280, Polysorbate 290, Polysorbate 300, Polysorbate 310, Polysorbate 320, Polysorbate 330, Polysorbate 340, Polysorbate 350, Polysorbate 360, Polysorbate 370, Polysorbate 380, Polysorbate 390, Polysorbate 400, Polysorbate 410, Polysorbate 420, Polysorbate 430, Polysorbate 440, Polysorbate 450, Polysorbate 460, Polysorbate 470, Polysorbate 480, Polysorbate 490, Polysorbate 500, Polysorbate 510, Polysorbate 520, Polysorbate 530, Polysorbate 540, Polysorbate 550, Polysorbate 560, Polysorbate 570, Polysorbate 580, Polysorbate 590, Polysorbate 600, Polysorbate 610, Polysorbate 620, Polysorbate 630, Polysorbate 640, Polysorbate 650, Polysorbate 660, Polysorbate 670, Polysorbate 680, Polysorbate 690, Polysorbate 700, Polysorbate 710, Polysorbate 720, Polysorbate 730, Polysorbate 740, Polysorbate 750, Polysorbate 760, Polysorbate 770, Polysorbate 780, Polysorbate 790, Polysorbate 800, Polysorbate 810, Polysorbate 820, Polysorbate 830, Polysorbate 840, Polysorbate 850, Polysorbate 860, Polysorbate 870, Polysorbate 880, Polysorbate 890, Polysorbate 900, Polysorbate 910, Polysorbate 920, Polysorbate 930, Polysorbate 940, Polysorbate 950, Polysorbate 960, Polysorbate 970, Polysorbate 980, Polysorbate 990, Polysorbate 1000.

Questions or comments?
877.722.7546

CliniCalm 1%
skin-soothing
corrective

hydrocortisone
anti-itch cream

03 | correct

2.1 oz (60 g)

formulated without:
synthetic dyes
synthetic fragrances

how it works:
1% hydrocortisone relieves skin irritation and itching while bisabolol and asiaticoside help reduce the appearance of visible redness, this topical cream also forms an effective barrier against moisture loss and helps protect skin against environmental stressors.



21168

CLINICALM
hydrocortisone cream

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68726-504

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

Inactive Ingredients

Ingredient Name	Strength
HYALURONATE SODIUM (UNII: YSE9PPT4TH)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
4-TERT-BUTYLCYCLOHEXANOL (UNII: K0H1405S9C)	
ALCOHOL (UNII: 3K9958V90M)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASIATICOSIDE (UNII: PKO39VY215)	
OATMEAL (UNII: 8PI54V663Y)	
LEVOMENOL (UNII: 24WE03BX2T)	
BUTYLENE GLYCOL (UNII: 3XUS85KORA)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
CERAMIDE NP (UNII: 4370DF050B)	
CETEARYL OLIVATE (UNII: 58B69Q84JO)	
GLYCERIN (UNII: PDC6A3C0OX)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
HONEY (UNII: Y9H1V576FH)	
HYALURONIC ACID (UNII: S270N0TRQY)	
HYDROXYPHENYL PROPAMIDOBENZOIC ACID (UNII: 25KRT26H77)	
LINSEED OIL (UNII: 84XB4DV00W)	
LYSINE HYDROCHLORIDE (UNII: JNJ23Q2COM)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PENTYLENE GLYCOL (UNII: 50C1307PZG)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
SORBITAN OLIVATE (UNII: MDL271E3GR)	
SOY SPHINGOLIPIDS (UNII: P491F5HP1U)	
SQUALANE (UNII: GW89575KF9)	
TOCOPHEROL (UNII: R0ZB2556P8)	
TRISODIUM ETHYLENEDIAMINE DISUCCINATE (UNII: YA22H34H9Q)	
TROPOLONE (UNII: 7L6DL16P1T)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
YEAST .BETA.-D-GLUCAN (UNII: 44FQ49X6UN)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68726-504-02	1 in 1 CARTON	07/01/2023	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:68726-504-01	7 g in 1 TUBE; Type 0: Not a Combination Product	07/01/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	07/01/2023	

Labeler - CP Skin Health Group, Inc. (611921669)

Revised: 6/2023

CP Skin Health Group, Inc.