

CLINICALM- hydrocortisone cream
CP Skin Health Group, Inc.

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 Olivat, Squalane, Olea Europaea (Olive) Fruit Oil, Sorbitan Olivat, 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

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)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	
4-TERT-BUTYLCYCLOHEXANOL (UNII: K0H1405S9C)	
ALCOHOL (UNII: 3K9958V90M)	
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)	
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)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	

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 Drug	M006	07/01/2023	

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

Revised: 12/2024

CP Skin Health Group, Inc.