

## **CLINICALM- hydrocortisone cream**

**Northwest Cosmetic Laboratories LLC, DBA Elevation Labs, Idaho**

*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.*

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### **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

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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© 2023 CP Skin Health Group, Inc.  
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, Stearalkene, Sulfur Dioxide, Hydroxyethyl Acrylate, Carbomer, Xanthan Gum, Hydroxyethyl Methacrylate, Carbomer, Hydroxyethyl Methacrylate, Carbomer, Xanthan Gum, Honey, Aloe Vera, Shea Butter, Keratin, Biotin, Chamomile Oil, Salicylic Acid, Tocopherol, Triethyl Citrate, Benzyl Alcohol, Hydroxyethyl Methacrylate, Hydroxyethyl Methacrylate, Carbomer, Xanthan Gum, Sodium Hydroxide, Hydroxyethyl Methacrylate, Carbomer, Xanthan Gum, Hydroxyethyl Methacrylate, Carbomer, Xanthan Gum.

**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.

Scan to learn more.



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**CLINICALM**

hydrocortisone cream

**Product Information**

**Product Type**

HUMAN OTC DRUG

**Item Code (Source)**

NDC:62282-504

**Route of Administration**

TOPICAL

**Active Ingredient/Active Moiety**

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

**Inactive Ingredients**

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

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:62282-504-02	1 in 1 CARTON	07/01/2023	
1		60 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:62282-504-01	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** - Northwest Cosmetic Laboratories LLC, DBA Elevation Labs, Idaho (929572014)

Revised: 6/2023

Northwest Cosmetic Laboratories LLC, DBA Elevation Labs, Idaho