

PHARMASKINCARE ACNECARE CREAM- hydrocortisone lotion

Spa de Soleil

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.

Pharmaskincare Acnecare Cream

Active Ingredient

Hydrocortisone 1%

Purpose

External Analgesic

Warnings

- For external use only.
- Avoid contact with the eyes
- If condition worsens or symptoms persist for more than seven days or clear up and occur again within a few days, stop use of this product and do not begin use of any hydrocortisone product until you have consulted a physician.
- Do not use for the treatment of diaper rash. Consult a physician.
- Keep out of reach of children.

Directions

Adults and children two years of age and older: Apply to affected area not more than three or four times daily. Children under two years of age: Do not use; consult a physician.

Uses:

For the temporary relief of itching associated with minor skin irritations and rashes. Other uses of this product should be only under the advice and supervision of a physician.

Inactive Ingredients:

Water, Caprylic/Capric Triglyceride, Glyceryl Stearate SE, Glycerin, Dimethicone, Propylene Glycol, Cetyl Alcohol, Sorbitol, Carthamus Tinctorius (Safflower) Seed Oil, **Squalane, Carbomer, Lactic Acid, Peg-4, Morus Alba Root Extract, Glycyrrhiza Glabra (Licorice) Root Extract, Kojic Acid, Butylene Glycol, Arctostaphylos Uva-Ursi Leaf Extract, Sodium Hydroxide, Ruscus Aculeatus Root Extract, Ginkgo Biloba Leaf Extract, Diospyros Kaki Fruit Extract, Betula Alba Bark Extract, DMAE, Thioctic Acid, Ubiquinone, *CO Glycerin, Citric Acid, Malic Acid, Gluconic Acid, Ascorbic Acid (Vitamin C), Malus Domestica Fruit Cell Culture Extract, Glycolic Acid, Salicylic Acid, Tartaric Acid, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, *CO Calendula Officinalis Flower Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract, *CO Citrus Limon (Lemon) Peel Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Camellia Sinensis Leaf Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spirulina Platensis Extract, Xanthan Gum, Lecithin, Tocopheryl Acetate (Vitamin E), Retinyl Palmitate (Vitamin A), Benzyl Alcohol, Dehydroacetic Acid

Warning

Keep out of reach of children.

Pharmaskincare Acnecare Soothing.jpg

Drug Facts

Active Ingredients / Purpose:
Hydrocortisone 1.0%. External Analgesic

Uses:
For the temporary relief of itching associated with minor skin irritations and rashes. Other uses of this product should be only under the advice and supervision of a physician.

Warnings:
• For external use only.
• Avoid contact with the eyes. If condition worsens or symptoms persist for more than seven 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 until you have consulted a physician.
• Do not use for the treatment of diaper rash, consult a physician.

Directions:
Adults and children 2 years of age and older: Apply to affected area not more than three to four times daily. **Children under 2 years of age:** Do not use. Consult a physician.

Inactive Ingredients:
Aqua, Propylene Glycol, Caprylic/Capric Triglyceride, Cyclopentasiloxane, Dimethicone, Stearic Acid, PEG-100 Stearate, Glycerol Stearate, Carbomer, Cetyl Alcohol, Jojoba Esters, Polyglyceryl-3 Beeswax, Polyglyceryl-6 Distearate, Salicylic Acid, Sodium Hydroxide, *CO Aloe Barbadensis Leaf Juice, Hydroxyethylcellulose, *CO Glycerin, DMAE, Ubiquinone, Thioctic Acid, Glycerin, *CO Hamamelis Virginiana (Witch Hazel) Extract, *CO Aweia Sativa (Oat) Kernel Extract, *CO Salix Alba (Willow) Bark Extract, *CO Pogostemon Cablin Leaf Extract, *CO Chamomilla Recutita (Matricaria) Flower Extract.

Drug Facts (continued)

Inactive Ingredients (continued):
*CO Citrus Limon (Lemon) Peel Extract, *CO Calendula Officinalis Flower Extract, *CO Humulus Lupulus (Hops) Extract, *CO Lavandula Angustifolia (Lavender) Flower/Leaf/Stem Extract, *CO Camellia Sinensis Leaf Extract, *CO Cucumis Sativus (Cucumber) Seed Extract, *CO Pyrus Malus (Apple) Fruit Extract, *CO Spirulina Platensis Extract, Ascorbic Acid (Vitamin C), Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), *CO Melaleuca Alternifolia (Tea Tree) Leaf Oil, Benzyl Alcohol, Fragrance, Dehydroacetic Acid.
***Certified Organic**

Indications: For the temporary relief of itching associated with minor skin irritations and rashes. Other uses of this product should be only under the advice and supervision of a physician.

Manufactured by Pharmaskincare®
Sun Valley, CA 91352 USA



MADE IN USA

Pharmaskincare® Advanced Science® Acnecare Soothing Cream is a nourishing moisturizer that helps restore hydration to the skin. Enriched with hydrocortisone and Aloe Vera, this product aids in easing redness and minor skin irritation for a soothing feel. Organic botanicals and apple fruit extract further enhance the relaxing properties of this calming formula. For maximum results, use daily with the Pharmaskincare Acnecare product line.



Pharmaskincare® has been at the forefront of the beauty industry, its ground-breaking technology making way for an innovative and unique approach to addressing various skin conditions. Each collection is designed to fuse nature's potent restorative powers with scientifically advanced ingredients. Harnessing the benefits of certified organic botanical extracts, alpha hydroxy acids, advanced peptides, vitamins, and more, Pharmaskincare offers skin gentle and effective formulations that provide the best possible care for your skin. From adolescence to maturity, Pharmaskincare has designed products that will guide your skin through each stage.

The Pharmaskincare® Advanced Science® Acnecare collection addresses many of the systemic causes of acne. For decades, salicylic acid and benzoyl peroxide have been at the front line of treating blemishes and breakouts. Pharmaskincare has used these ingredients and taken them a step further by combining their powerful acne-fighting properties with nourishing and hydrating botanicals. The Acnecare collection effectively works to keep breakouts at bay without overly drying the skin, making way for a soothed, clear, and healthy complexion.

Pharmaskincare® is committed to making products that are environmentally conscious and free of parabens, sulfates, dyes, mineral oils and lanolin.



Drug Facts

Active Ingredients / Purpose:
Hydrocortisone 1.0%. External Analgesic

Uses: For the temporary relief of itching associated with minor skin irritations and rashes. Other uses of this product should be only under the advice and supervision of a physician.

Warnings: • For external use only. • Avoid contact with the eyes. If condition worsens or symptoms persist for more than seven 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 until you have consulted a physician. • Do not use for the treatment of diaper rash, consult a physician.

Directions: Adults and children 2 years of age and older: Apply to affected area not more than three to four times daily. **Children under 2 years of age:** Do not use. Consult a physician.

www.pharmaskincare.com
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Sun Valley, CA 91352 USA



MADE IN USA

PHARMASKINCARE ACNECARE CREAM
hydrocortisone lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9108
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	0.025 mg in 2.5 mL

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
WATER (UNII: 059QF0K00R)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9108-1	60 mL in 1 TUBE; Type 0: Not a Combination Product	10/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	10/10/2017	

Labeler - Spa de Soleil (874682867)**Establishment**

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-9108)

Revised: 10/2017

Spa de Soleil