

**ACNECARE DERMACONTROL CREAM- salicylic acid liquid
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.

Acnecare Dermacontrol Cream

Active ingredient Purpose

Benzoyl Peroxide (5%).....Acne Treatment

Purpose

Acne Treatment

For treatment of acne

Warnings

For external use only

Avoid contact with eyes. If contact occurs, rinse thoroughly with water.

If swallowed, get medical help or contact a Poison Control Center right away. If excessive skin irritation develops or increases, discontinue use and consult a doctor. Keep out of reach of children.

Keep out of reach of children. In case of accidental ingestion, get medical help or contact a Poison Control Center right away.

When using this product

- Skin irritation and dryness is more likely to occur if you use another topical acne medication while using this product. If irritation occurs, use only one topical acne medication at a time.

Directions:

Clean the skin thoroughly before applying this product. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. . If bothersome dryness or peeling occurs, reduce application to once a day or every other day. . If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and consult a doctor.

Sensitivity test for a new user: Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions as stated.

Other Ingredients:

Aqua, Caprylic/Capric Triglyceride, Cetyl Alcohol, Ethoxydiglycol, Polyglyceryl-6 Distearate, Stearic Acid, Dimethicone, Jojoba Esters, Carbomer, Lactic Acid, Glycolic Acid, Hydroxyethylcellulose, Sodium Hydroxide, Polyglyceryl-3 Beeswax, Sodium PCA, Citrus

Aurantium Bergamia (Bergamot) Peel Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, BHT, Titanium Dioxide, *CO Glycerin, Glycerin, Citric Acid, Malic Acid, DMAE, Ubiquinone, Thioctic Acid, Gluconic Acid, Ascorbic Acid (Vitamin C), 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, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Benzyl Alcohol, Dehydroacetic Acid.
*Certified Organic

Drug Facts
Active Ingredients / Purpose: Benzoyl Peroxide 5.0%...Acne Treatment
Uses: For the treatment of acne.
Warnings: <ul style="list-style-type: none"> For external use only. When using this product: skin irritation and dryness are more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time. Avoid unnecessary sun exposure and use a sunscreen. Avoid contact with the eyes, lips, and mouth. Avoid contact with hair and dyed fabrics, which may be bleached by this product. Skin irritation may occur, characterized by redness, burning, itching, peeling, or possibly swelling. Irritation may be reduced by using the product less frequently or in a lower concentration. Stop use and ask a doctor if irritation becomes severe. Do not use if you: <ul style="list-style-type: none"> Have very sensitive skin; or Are sensitive to benzoyl peroxide.
Directions: Clean the skin thoroughly before applying this product. Cover the entire affected area with a thin layer one to three times daily. Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three times daily if needed or as directed by a doctor. <ul style="list-style-type: none"> If bothersome dryness or peeling occurs, reduce application to once a day or every other day. If going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and consult a doctor. Sensitivity test for a new user: Apply product sparingly to one or two small affected areas during the first three days. If no discomfort occurs, follow the directions as stated.

Drug Facts (continued)
Inactive Ingredients: Aqua, Caprylic/Capric Triglyceride, Cetyl Alcohol, Ethoxydiglycol, Polyglyceryl-6 Distearate, Stearic Acid, Dimethicone, Jojoba Esters, Carbomer, Lactic Acid, Glycolic Acid, Hydroxyethylcellulose, Sodium Hydroxide, Polyglyceryl-3 Beeswax, Sodium PCA, Citrus Aurantium Bergamia (Bergamot) Peel Oil, Melaleuca Alternifolia (Tea Tree) Leaf Oil, BHT, Titanium Dioxide, *CO Glycerin, Glycerin, Citric Acid, Malic Acid, DMAE, Ubiquinone, Thioctic Acid, Gluconic Acid, Ascorbic Acid (Vitamin C), 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, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Benzyl Alcohol, Dehydroacetic Acid. *Certified Organic
Manufactured by Pharmaskincare® Sun Valley, CA 91352 USA

MADE IN USA
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®

ADVANCED SCIENCE®

ACNECARE™

DERMACONTROL

C R E A M

ACNE TREATMENT

2 fl oz e 60 mL

ACNECARE DERMACONTROL CREAM

salicylic acid liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-8090
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE - UNII:W9WZN9A0GM)	BENZOYL PEROXIDE	3 mg in 60 mL

Inactive Ingredients

Ingredient Name	Strength
CETYL ALCOHOL (UNII: 936JST6JCN)	
WATER (UNII: 059QF0KO0R)	
ETHOXYDIGLYCOL OLEATE (UNII: 843B4EZ H9X)	
CAPRYLIC/CAPRIC ACID (UNII: DI775RT244)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-8090-1	60 mL in 1 TUBE; Type 0: Not a Combination Product	12/23/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M006	12/23/2022	

Labeler - Spa de Soleil (874682867)

Registrant - Spa de Soleil (874682867)

Establishment

Name	Address	ID/FEI	Business Operations
Spa de Soleil		874682867	manufacture(68062-8090)

Revised: 12/2022

Spa de Soleil