PHARMASKINCARE ACNECARE DERMACONTROL CREAM- benzoyl peroxide 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 Dermacontrol Cream

Active Ingredient

Benzoyl Peroxide 5.0%

Purpose

Acne Treatment

Warnings

- For external use only.
- When using this product : skin irritation and dryness is 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:

- have very sensitive skin
- are sensitive to benzoyl peroxide

Directions

Clean the skin thoroughly before applying this product. Cover the entire affected area with a thin layer and rinse thoroughly 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 ask a doctor.

Sensitivity Test for a New User. Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated

Uses:

For the treatment of acne.

Inactive Ingredients:

Water, Stearic Acid, Cetyl Alcohol, Ethoxydiglycol, Caprylic/Capric Triglyceride, Carbomer, Dimethicone, Jojoba Esters, Polyglyceryl-3 Beeswax, Polyglyceryl-6 Distearate, Lactic Acid, Glycolic Acid, Hydroxyethylcellulose, Sodium Hydroxide, 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), Malus Domestica Fruit Cell Culture Extract, 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, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Benzyl Alcohol, Dehydroacetic Acid

Warning

Keep out of reach of children.

Do Not Use

Do not use if you:

- have very sensitive skin
- are sensitive to benzoyl peroxide

Pharmaskincare AcnecareDermacontrol.jpg







Pharmaskincare® Advanced Science® Acnecare Dermacontrol Cream targets problem areas with its effective acne control properties, working to control breakouts, reduce blemishes, and clarify the complexion. It is fortified with benzoyl peroxide and glycolic acid to exfoliate and brighten the skin and is enriched with sodium PCA, a natural emollient that works to keep skin moisturized and balanced. For maximum results, use daily with the Pharmaskincare Acnecare line.

Pharmaskincare® has been at the forefront of the beauty industry, its ground-breaking technology making 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.

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





PHARMASKINCARE ACNECARE DERMACONTROL CREAM

benzoyl peroxide lotion

| Product Information | ion | | | | | | | |
|---|-----------------|-------------------------------|--------------------------------|-----------|---------------|-------|-----------------------|--|
| Product Type | | HUMAN OTC DRUG | TC DRUG Item Code (Source) NDC | | | NDC:6 | C:68062-9109 | |
| Route of Administrat | | | | | | | | |
| | | | | | | | | |
| Active Ingredient | Active Moi | ety | | | | | | |
| Ingredient Name Basis of Streng | | | | | | | Strength | |
| BENZOYL PEROXIDE (UNII: W9WZN9A0GM) (BENZOYL PEROXIDE -BENZOYLUNII: W9 WZN9A0GM)PEROXIDE | | | | | | | 0.063 mg in 2.5 mL | |
| | | | | | | | | |
| Inactive Ingredie | nts | | | | | | | |
| Ingredient Name | | | | | | | Strength | |
| CETYL ALCOHOL (UN | NII: 936JST6JCI | V) | | | | | | |
| WATER (UNII: 059QF0K00R) | | | | | | | | |
| GLYCERIN (UNII: PDC6A3C0OX) | | | | | | | | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Packaging | | | | | | | | |
| # Item Code | | Package Description | N | Marketin | ig Start Date | Mai | rketing End Date | |
| 1 NDC:68062-9109-1 | 60 mL in 1 TUE | BE; Type 0: Not a Combination | Product 10 | 0/10/2017 | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Marketing Info | rmation | | | | | | | |
| Marketing Category | | on Number or Monograph C | itation | Marketi | ng Start Date | Ma | rketing End Date | |
| OTC monograph final | part333D | - · · | | 0/10/2017 | | | | |
| | | | | | | | | |

Labeler - Spa de Soleil (874682867)

| Establishment | | | | | | | | |
|---------------|---------|-----------|-------------------------|--|--|--|--|--|
| Name | Address | ID/FEI | Business Operations | | | | | |
| Spa de Soleil | | 874682867 | manufacture(68062-9109) | | | | | |

Revised: 10/2017

Spa de Soleil