

## **PHARMASKINCARE ACNECARE EXFOLIATOR- salicylic acid solution**

### **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.*

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### **Pharmaskincare Acnecare Exfoliator**

#### **Active Ingredient**

Salicylic Acid 0.5%

#### **Purpose**

Acne Treatment

#### **Warnings**

##### 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.

#### **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.

Massage Acnecare Exfoliator onto cleansed, damp skin with fingertips using a circular motion. Rinse well with lukewarm water and pat dry. Avoid use on flare-ups and breakouts.

#### **Uses:**

For the treatment of acne.

#### **Inactive Ingredients:**

Water, Phytelephas Aequatorialis Seed Powder, Glycerin, Glyceryl Stearate SE, Cocamidopropyl Betaine, Carthamus Tinctorius (Safflower) Seed Oil, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, Hydroxyethylcellulose, \*CO Glycerin, \*CO Aloe Barbadosensis Leaf Juice, Ananas Sativus (Pineapple) Fruit Extract, Helianthus Annuus (Sunflower) Seed Oil, Papain, \*CO Aesculus Hippocastanum (Horse Chestnut) Seed Extract, \*CO Prunus Armeniaca (Apricot) Fruit Extract, \*CO Rosa Centifolia Flower Extract, \*CO Rosmarinus Officinalis (Rosemary) Leaf Extract, \*\*Squalane, DMAE, Thioctic Acid, Ubiquinone, Carica Papaya (Papaya) Fruit Extract, Sea Salt (Dead Sea Salt), Malus Domestica Fruit Cell Culture Extract, Xanthan Gum, Citric Acid, Lactic Acid, Malic Acid, Gluconic Acid, Ascorbic Acid (Vitamin C), Lecithin, Glycolic Acid, Tartaric Acid, Tocopheryl Acetate (Vitamin E), Retinyl Palmitate (Vitamin A), Benzyl Alcohol, Fragrance, Dehydroacetic Acid

#### **Warning**

**Keep out of reach of children.**

Pharmaskincare AcnecareExfoliator.jpg

<b>Drug Facts</b>
<b>Active Ingredients / Purpose:</b> Salicylic Acid 0.5%.....Acne Treatment
<b>Uses:</b> For the treatment of acne.
<b>Warnings:</b> • 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.
<b>Directions:</b> Clean the skin thoroughly before applying this product. Cover the entire affected area once a day. Because excessive drying of the skin may occur, start with one application every day, and if excessive dryness occurs, reduce to once every other day. Massage Acnecare Exfoliator onto cleansed, damp skin with fingertips using a circular motion. Rinse well with lukewarm water and pat dry. Avoid use on flare-ups and breakouts.
<b>Inactive Ingredients:</b> Aqua, Phytelphas Aequatorialis Seed Powder, Glycerin, Glyceryl Stearate SE, Cocamidopropyl Betaine, Carthamus Tinctorius (Safflower) Seed Oil, Glyceryl Stearate, PEG-100 Stearate, Stearic Acid, Hydroxyethylcellulose, *CO Glycerin, *CO Aloe Barbadosensis Leaf Juice, Ananas Sativus (Pineapple) Fruit Extract, Helianthus Annuus (Sunflower) Seed Oil, Papain, *CO Aesculus Hippocastanum (Horse Chestnut) Seed Extract, *CO Prunus Ameriaca (Apricot) Fruit Extract, *CO Rosa Centifolia Flower Extract, *CO Rosmarinus Officinalis (Rosemary) Leaf Extract, **Squalane, DMAE, Thioctic Acid, Ubiquinone, Carica Papaya (Papaya) Fruit Extract, Sea Salt (Dead Sea Salt), Citric Acid, Lactic Acid, Malic Acid, Gluconic Acid, Ascorbic Acid (Vitamin C), Glycolic Acid, Tartaric Acid, Retinyl Palmitate (Vitamin A), Tocopheryl Acetate (Vitamin E), Benzyl Alcohol, Fragrance, Dehydroacetic Acid. *Certified Organic, **From Sugarcane
Manufactured by Pharmaskincare® Sun Valley, CA 91352 USA
    
MADE IN USA

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.

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



**Pharmaskincare® Advanced Science® Acnecare Exfoliator** is uniquely formulated with salicylic acid, papaya enzyme, and pineapple extract to deeply and thoroughly remove pore-clogging impurities. A perfect way to help maintain clear and calm skin, this scrub gently removes dead cells, helping to prevent future breakouts. Organic botanical extracts work to calm and nourish the skin for a healthy, balanced feel. For maximum results use with the Pharmaskincare Acnecare product line.

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.



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<b>Directions:</b> Clean the skin thoroughly before applying this product. Cover the entire affected area once a day. Because excessive drying of the skin may occur, start with one application every day, and if excessive dryness occurs, reduce to once every other day. Massage Acnecare Exfoliator onto cleansed, damp skin with fingertips using a circular motion. Rinse well with lukewarm water and pat dry. Avoid use on flare-ups and breakouts.



## PHARMASKINCARE ACNECARE EXFOLIATOR

salicylic acid solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68062-9110
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SALICYLIC ACID (UNII: O414PZ4LPZ) (SALICYLIC ACID - UNII:O414PZ4LPZ)	SALICYLIC ACID	0.013 mg in 2.5 mL

### Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
SAFFLOWER OIL (UNII: 65UEH262IS)	
PHYTELEPHAS AEQUATORIALIS SEED (UNII: 2DJN5A6ONH)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68062-9110-1	120 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 final	part333D	10/10/2017	

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

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Spa de Soleil		874682867	manufacture(68062-9110)

Revised: 10/2017

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