# PHARMASKINCARE SOLAR-C MOISTURIZER SPF 30- titanium dioxide 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.

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#### Pharmaskincare Solar-C Moisturizer SPF 30

#### **Active Ingredient**

Titanium Dioxide 10.5%

#### **Purpose**

Sunscreen

#### Warnings

- For external use only.
- Do not use on broken or damaged skin
- When using this product, keep out of eyes. Rinse with water to remove.
- Stop use and ask a doctor is rash or irritation occurs or lasts.
- If swallowed, seek medical help or contact a poison control center right away.
- Keep out of reach of children.

#### **Directions**

Apply every morning as a daily moisturizer. Apply generously and evenly 15 minutes before sun exposure. Reapply at least every two hours. Use a water-resistant sunscreen if swimming or sweating. Children under six months of age: consult a doctor before use.

#### Other Information

Protect the product in this container from excessive heat.

#### Uses:

Helps prevent sunburn. Higher SPF gives more sunburn protection. Designed for skin highly sensitive to sunburn. If used as directed with other sun protection measures (see Sun Alert) decreases the risk of skin cancer and early skin aging caused by the sun.

Sun Alert: Spending time in the use increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad-spectrum SPF value of 15 or higher and other sun protection measures such as limited time in the sun, especially from 10 a.m. to 2 p.m. Wear long pants, hats, sunglasses, and long-sleeve shirts.

#### **Inactive Ingredients:**

Water, Cocos Nucifera (Coconut) Oil, Carthamus Tinctorius (Safflower) Seed Oil, Cetyl Alcohol, Caprylic/Capric Triglyceride, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Titanium Dioxide, Polyglyceryl-3 Beeswax, Polyglyceryl-6 Distearate, Jojoba Esters, Polyhydroxystearic Acid, Carbomer, \*CO Glycerin, Sodium Hydroxide, Thymus Vulgaris (Thyme) Leaf Extract, Rosa Canina Fruit Extract, Gardenia Florida Fruit Extract, Fucus Vesiculosus Extract, \*CO Carum Petroselinum

(Parsley) Extract, \*CO Centella Asiatica Leaf Extract, \*CO Cucumis Sativus (Cucumber) Seed Extract, \*CO Daucus Carota Sativa (Carrot) Root Extract, \*CO Euphrasia Officinalis Extract, Benzyl Alcohol, Disodium EDTA, Dehydroacetic Acid

#### Warning

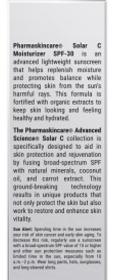
#### Keep out of reach of children.

Pharmaskincare SolarC SPF 30













titanium dioxide lotion

<b>Product Information</b>
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Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68062-9099
I Toduct I ypc	1101/211 010 2100	item code (Source)	112010000

Route of Administration TOPICAL

### **Active Ingredient/Active Moiety**

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Ingredient Name	Basis of Strength	Strength
TITANII IM DIO XIDE (LINII: 15EIX9V2IP) (TITANII IM DIO XIDE - LINII: 15EIX9V2IP	TITANII IM DIO XIDE	0.2625 mg in 2.5 mL

Inactive Ingredients

Ingredient Name
Strength

MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)

WATER (UNII: 059QF0K00R)

COCONUT OIL (UNII: Q9L0O73W7L)

SAFFLOWER OIL (UNII: 65UEH262IS)

CETYL ALCOHOL (UNII: 936JST6JCN)

GLYCERIN (UNII: PDC6A3C0OX)

# **Packaging**

	# Item Code	Package Description	Marketing Start Date	Marketing End Date
l	1 NDC:68062-9099-1	120 mL in 1 TUBE; Type 0: Not a Combination Product	10/10/2017	

# **Marketing Information**

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Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part352	10/10/2017		

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

# Establishment Name Address ID/FEI Business Operations Spa de Soleil 874682867 manufacture(68062-9099)

Revised: 12/2018 Spa de Soleil