## PHARMASKINCARE SOLAR-C MOISTURIZER SPF 15- zinc oxide 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 15

#### **Active Ingredient**

Zinc Oxide 5.3%

#### **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. 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 15







Pharmankinean+III Solar C Mointarior SPF-15 is a cashiner-soft formula that Diarlets the skin with exceedabl visions to promote hydration and protect skin from damaging sen right. This daily, huminous cream combines case protection fractive and articulation to protect and promote healthy, whence dails.

The Pharmankincan+III Advanced Science/III Solar C collection is specifically designed to aid in skin protection and relywersation by Tasing bread spectrum SPF with related in the protection of the second oil, and corner extract. This ground-breaking bread spectrum SPF with related in received protects that or delip protect the skin but also work to restore and enhance skin stally.

Pharmankincare/S is committed to making products that are environmentally conscious and five of paraboxin. said late, type, mineral as but and









# PHARMASKINCARE SOLAR-C MOISTURIZER SPF 15 zinc oxide lotion

| Product Information     |                |                    |                |
|-------------------------|----------------|--------------------|----------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:68062-9100 |
| Route of Administration | TOPICAL        |                    |                |
|                         |                |                    |                |

| Active Ingredient/Active Moiety                              |                   |                   |  |
|--|-------------------|-------------------|--|
| Ingredient Name  | Basis of Strength | Strength          |  |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE        | 0.13 mg in 2.5 mL |  |

| Inactive Ingredients                          |          |  |  |
|---|----------|--|--|
| Ingredient Name                               | Strength |  |  |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) |          |  |  |
| WATER (UNII: 059QF0KO0R)                      |          |  |  |
| COCONUT OIL (UNII: Q9L0O73W7L)                |          |  |  |
| SAFFLOWER OIL (UNII: 65UEH262IS)              |          |  |  |
| CETYL ALCOHOL (UNII: 936JST6JCN)              |          |  |  |
| GLYCERIN (UNII: PDC6A3C0OX)                   |          |  |  |

| Packaging                       |   |                             |                           |
|---------------------------------|---|-----------------------------|---------------------------|
| # Item Code Package Description |   | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
| 1 NDC:68062-9100-1              | 50 mL in 1 JAR; 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   | part352                                  | 10/10/2017           |                    |
|                       |  |                      |                    |

### Labeler - Spa de Soleil (874682867)

| Establishment |         |           |                         |  |
|---------------|---------|-----------|-------------------------|--|
| Name          | Address | ID/FEI    | Business Operations     |  |
| Spa de Soleil |         | 874682867 | manufacture(68062-9100) |  |

Revised: 10/2017 Spa de Soleil