

BIOSOLIS MELT IN SUN SPF30- titanium dioxide cream

Pro Vera SA

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.

BIOSOLIS Melt in Sun Cream SPF30

Drug Facts

Active ingredients

Titanium Dioxide 7.5%

Purpose

Sunscreen

Uses

- helps prevent sunburn.
- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For external use only

Do not use

- on damaged or broken skin

When using this product

keep out of eyes. Rinse with water to remove

Stop use and ask a doctor if

- rash occurs

Keep out of reach of children.

If swallowed, get medical help or contact Poison Control Center right away

Directions

- Apply liberally 15 minutes before sun exposure
- Reapply at least every 2 hours
- Use a water resistant sunscreen if swimming or sweating
- **Sun Protection Measures:** Spending time in the sun 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 including:
 - Limit time in the sun, especially from 10 a.m. – 2 p.m.
 - Wear long-sleeved shirts, pants, hats and sunglasses
 - Children under 6 months of age: Ask a doctor

Other information

- Protect the product in this container from excessive heat and direct sun.

Inactive ingredients

BRASSICA CAMPESTRIS (SEED) OIL*, DICAPRYLYL CARBONATE, CAPRYLIC/ CAPRIC TRIGLYCERIDE, C10-C18 TRIGLYCERIDES, SESAMUM INDICUM SEED OIL*, PONGAMIA GLABRA SEED OIL*, DIETHYL SEBACATE, HYDROGENATED CASTOR OIL, STEARIC ACID, ALUMINUM HYDROXYDE, POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE, PARFUM, TOCOPHERO.

Questions or comments?

info@biosolis.info or Call **Adverse Event Reporting:** 1-866-8539427

Package Labeling:



Drug Facts

Active ingredients Purpose

Titanium Dioxide 7.5% }... Sunscreen

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*Ingredient from Organic Farming
100% of the total ingredients are from natural origin
47.70% of the total ingredients are from organic farming

Drug Facts (continued)

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Questions or comments?

info@biosolis.info or Call

Adverse Event Reporting:
1-866-8539427

Licensee and US importer:

Cosmorganic Inc, NY
60 Broad Street Suite 3502
New York - NY 10004

BIOSOLIS is manufactured by

Pro-Vera SA
Avenue Thomas Edison 80
1402 Thines (Nivelles)
Belgium
www.biosolis.info

Made in Belgium



BIOSOLIS[®]
ORGANIC CERTIFIED SUNCARE



Melt-In Sun Cream

High Protection
Normal to Very Dry Skins
Unique Texture



3.4 FL.OZ (100ml)



COSMETIQUE BIOLOGIQUE

Natural Cosmetic certified by ECOCERT Greenlife according to ECOCERT Standard available at : <http://cosmetics.ecocert.com>
100% of the total ingredients are from natural origin.
45,70% of the total ingredients are from organic farming.



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Best before:



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Melt-In Sun Cream

High Protection
Face and Body
Normal to Very Dry Skins
Unique Texture



3.4 FL.OZ (100ml)

Drug Facts

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Other information

Unit not for sale, please see outer box for complete drug facts informations.

Questions or comments? info@biosolis.info or Call

Adverse Event Reporting: 1-866-8539427



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BIOSOLIS MELT IN SUN SPF30

titanium dioxide cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:61296-007 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP) | TITANIUM DIOXIDE | 75 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| BRASSICA RAPA SUBSP. OLEIFERA OIL (UNII: N4G8379626) | |
| DICAPRYLYL CARBONATE (UNII: 609A3V1SUA) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| C10-18 TRIGLYCERIDES (UNII: 43AGM4PHPI) | |
| SESAME OIL (UNII: QX10HYY4QV) | |
| KARUM SEED OIL (UNII: 62160PU6FJ) | |
| DIETHYL SEBACATE (UNII: I41B9FJK6V) | |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| POLYGLYCERYL-2 DIPOLYHYDROXYSTEARATE (UNII: 9229XJ4V12) | |

TOCOPHEROL (UNII: R0ZB2556P8)

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:61296-007-00 | 1 in 1 BOX | 02/01/2019 | |
| 1 | | 100 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part352 | 02/01/2019 | |

Labeler - Pro Vera SA (375713286)

Revised: 1/2019

Pro Vera SA