**BROAD SPECTRUM SPF 30 UP THE ANTI - titanium dioxide and zinc oxide cream**
**Biopelle, Inc.**

*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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**Broad Spectrum SPF 30 Up The Anti**

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**Active Ingredients**
Zinc Oxide 6.0%
Titanium Dioxide 3.2%

**Purpose**

Sunscreen

**Uses**
- helps prevent sunburn
- if used as directed with other sun protections 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 product is swallowed, get medical help or contact a Poison Control Center right away.

**Directions**
- apply to face and under throat after cleansing
- reapply:
- - after excessive perspiration
- **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 15 or higher and other sun protection measures including:
- - limit time in the sun, especially from 10 a.m. - 2 p.m.
  - wear long sleeve shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor

**Inactive Ingredients**

water, ethylhexyl palmitate, cyclopentasiloxane, c12-15 alkyl benzoate, dimethicone, polysorbate 80, peg-100 stearate, glyceryl stearate, propylene glycol, polyglyceryl-6 isostearatem cetyl alcohol, sodium acrylate/sodium acryloyldimethyl laurate copolymer, glycerin, cyclohexasiloxane, caprylyl methicone, alumina, isohexadecane, boron nitride, triethoxysilylethyl polydimethylsiloxy hexyl dimethicone, sodium levulinate, lauryl peg-9 polydimethylsiloxyethyl dimethicone, acrylates/ammonium methacrylate copolymer, phenoxyethanol, polyhydroxystearic acid, sodium anisate, triethoxycaprylylsilane, panthenol, iodopropynyl butylcarbamate, dmdm hydantoin, aloe barbadensis leaf juice, allantoin, disodium edta, methylparaben, ethylparaben, butylparaben, butylene glycol, propylparaben, isobutylparaben, chamomilla recutita (matricaria) flower extract, camellia sinensis leaf extract, iron oxides.

**Other Information**

- protect this product from excessive heat and direct sun

**Questions or comments?**

Call toll free 1-866-424-6735 (weekdays)

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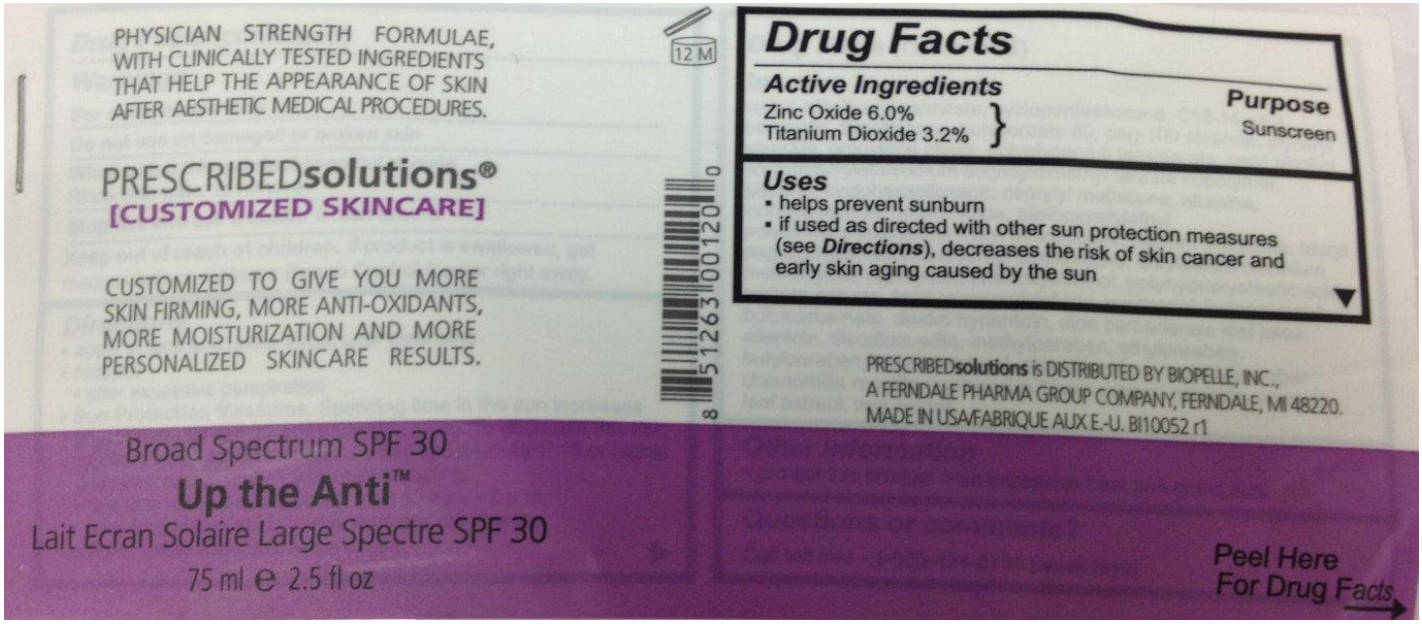
A Ferndale Pharma Group Company, Ferndale, MI 48220

Made In USA

**Broad Spectrum SPF 30 Up The Anti 75ml (42485-005-01)**



**Drug Facts** (continued)

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**Drug Facts** (continued)

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water, ethylhexyl palmitate, cyclopentasiloxane, C12-15 alkyl benzoate, dimethicone, polysorbate 80, peg-100 stearate, glyceryl stearate, propylene glycol, polyglyceryl-6 isostearate, cetyl alcohol, sodium acrylate/sodium acryloyldimethyl taurate copolymer, glycerin, cyclohexasiloxane, caprylyl methicone, alumina, isohexadecane, boron nitride, triethoxysilylethyl polydimethylsiloxyethyl hexyl dimethicone, sodium levulinate, lauryl peg-9 polydimethylsiloxyethyl dimethicone, acrylates/ammonium methacrylate copolymer, phenoxyethanol, polyhydroxystearic acid, sodium anisate, triethoxycaprylylsilane, panthenol, iodopropynyl butylcarbamate, dmdm hydantoin, aloe barbadensis leaf juice, allantoin, disodium edta, methylparaben, ethylparaben, butylparaben, butylene glycol, propylparaben, isobutylparaben, chamomilla recutita (matricaria) flower extract, camellia sinensis leaf extract, iron oxides.

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# BROAD SPECTRUM SPF 30 UP THE ANTI

titanium dioxide, zinc oxide cream

## Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:42485-005 |
| **Route of Administration** | TOPICAL | **DEA Schedule** | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 32 mg in 1 mL |
| **ZINC OXIDE** (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 60 mg in 1 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **WATER** (UNII: 059QF0KO0R) | |
| **ETHYLHEXYL PALMITATE** (UNII: 2865993309) | |
| **CYCLOMETHICONE 5** (UNII: 0THT5PCI0R) | |
| **C12-15 ALKYL BENZOATE** (UNII: A9EJ3J61HQ) | |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) | |
| **POLYSORBATE 80** (UNII: 6OZP39ZG8H) | |
| **PEG-100 STEARATE** (UNII: YD01N1999R) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **SODIUM ACRYLATE/SODIUM ACRYLOYLDIMETHYLTAURATE COPOLYMER (4000000 MW)** (UNII: 1DXE3F3OZX) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **CYCLOMETHICONE 6** (UNII: XHK3U310BA) | |

| | |
|---|---|
| **CAPRYLYL TRISILOXANE** (UNII: Q95M2P1KJL) | |
| **ALUMINUM OXIDE** (UNII: LMI26O6933) | |
| **ISOHEXADECANE** (UNII: 918X1OUF1E) | |
| **BORON NITRIDE** (UNII: 2U4T60A6YD) | |
| **SODIUM LEVULINATE** (UNII: VK44E1MQU8) | |
| **PHENOXYETHANOL** (UNII: HIE492ZZ3T) | |
| **POLYHYDROXYSTEARIC ACID (2300 MW)** (UNII: YXH47AOU0F) | |
| **SODIUM ANISATE** (UNII: F9WFJ28MV9) | |
| **TRIETHOXYCAPRYLYLSILANE** (UNII: LDC331P08E) | |
| **PANTHENOL** (UNII: WV9CM0O67Z) | |
| **IODOPROPYNYL BUTYLCARBAMATE** (UNII: 603P14DHEB) | |
| **ALOE VERA LEAF** (UNII: ZY81Z83H0X) | |
| **DMDM HYDANTOIN** (UNII: BYR0546TOW) | |
| **ALLANTOIN** (UNII: 344S277G0Z) | |
| **EDETATE SODIUM** (UNII: MP1J8420LU) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **ETHYLPARABEN** (UNII: 14255EXE39) | |
| **BUTYLPARABEN** (UNII: 3QPI1U3FV8) | |
| **BUTYLENE GLYCOL** (UNII: 3XUS85K0RA) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **ISOBUTYLPARABEN** (UNII: 0QQJ25X58G) | |
| **MATRICARIA CHAMOMILLA WHOLE** (UNII: 2Z4LRR776S) | |
| **CAMELLIA SINENSIS WHOLE** (UNII: C5M4585ZBZ) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:42485-005-01 | 75 mL in 1 BOTTLE | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part352 | 11/14/2012 | |

## Labeler - Biopelle, Inc. (808158823)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| Englewood Lab, LLC | | 172198223 | manufacture(42485-005) |

Revised: 11/2012 Biopelle, Inc.