

**BROAD SPECTRUM SPF 30 UP THE ANTI - titanium dioxide, 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 isostearate, cetyl alcohol, sodium acrylate/sodium acryloyldimethyl laurate copolymer, glycerin, cyclohexasiloxane, caprylyl methicone, alumina, isoheaxadecane, 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)

PRESCRIBEDsolutions is Distributed By Biopelle, Inc.

A Ferndale Pharma Group Company, Ferndale, MI 48220

Made In USA

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

PHYSICIAN STRENGTH FORMULAE, WITH CLINICALLY TESTED INGREDIENTS THAT HELP THE APPEARANCE OF SKIN AFTER AESTHETIC MEDICAL PROCEDURES.

**PRESCRIBEDsolutions®**  
[CUSTOMIZED SKINCARE]

CUSTOMIZED TO GIVE YOU MORE SKIN FIRING, MORE ANTI-OXIDANTS, MORE MOISTURIZATION AND MORE PERSONALIZED SKINCARE RESULTS.

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Drug Facts	
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<b>Uses</b>	
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Broad Spectrum SPF 30  
**Up the Anti™**  
Lait Ecran Solaire Large Spectre SPF 30  
75 ml e 2.5 fl oz

Peel Here  
For Drug Facts →

**Drug Facts (continued)****Warnings**

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**BROAD SPECTRUM SPF 30 UP THE ANTI**

titanium dioxide, zinc oxide cream

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:42485-005
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
TITANIUM DIOXIDE (UNII: 15FIX9 V2JP) (TITANIUM DIOXIDE - UNII:15FIX9 V2JP)	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: 059QF0K00R)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
CYCLOMETHICONE 5 (UNII: 0THT5PC10R)	
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 (400000 MW) (UNII: 1DXE3F3OZX)	
GLYCERIN (UNII: PDC6A3C0OX)	
CYCLOMETHICONE 6 (UNII: XHK3U310BA)	

CAPRYLYL TRISILOXANE (UNII: Q95M2P1KJL)
ALUMINUM OXIDE (UNII: LM26O6933)
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: WV9CM0067Z)
IODOPROPYNYL BUTYLCARBAMATE (UNII: 603P14DHEB)
ALOE VERA LEAF (UNII: ZY81Z83H0X)
DMDM HYDANTOIN (UNII: BYR0546TOW)
ALLANTOIN (UNII: 344S277G0Z)
EDETATE SODIUM (UNII: MP1J8420LU)
METHYL PARABEN (UNII: A2I8C7HI9T)
ETHYL PARABEN (UNII: 14255EXE39)
BUTYL PARABEN (UNII: 3QP1I03FV8)
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)
PROPYL PARABEN (UNII: Z8IX2SC1OH)
ISOBUTYL PARABEN (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)