

STOP THE CLOCK BROAD SPECTRUM SPF 50 - avobenzone, homosalate, 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.

Stop the Clock Broad Spectrum SPF 50

Active Ingredients

Avobenzone 3%

Homosalate 7%

Titanium Dioxide 3.5%

Zinc Oxide 1%

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 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, butylene glycol dicaprylate/dicaprate, c12-15 alkyl benzoate, sodium hyaluronate, hydrolyzed

potato protein, gamma aminobutyric acid, decamethylcyclopentasiloxane, polysilicone-15, c18-36 acid triglyceride, hexapeptide-11, silica, dipalmitoyl hydroxyproline, polyacrylate-13, hexanoyl dipeptide-3 norleucine acetate, thermus thermophilus ferment, uncaria tomentosa extract, porphyra umbilicalis extract, sodium tocopheryl phosphate, hydrolyzed vegetable protein, adenosine triphosphate, acetyl tyrosine, proline, sodium stearoyl glutamate, dimethicone, dimethiconol, cyclopentasiloxane, lecithin, sodium lactate, triethoxycaprylylsilane, cyclomethicone, peg-10 dimethicone, silica dimethyl silylate, glycerin, polyisobutene, polysorbate 20, phenoxyethanol, caprylyl glycol, butylene glycol, citric acid, xanthan gum, hexylene glycol, disodium edta, methicone, alcohol, eugenol

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.

www.BIOPELLE.com

MADE IN USA

Package Label

Principal Display

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.

Drug Facts

Active Ingredients

- Avobenzone 3%
- Homosalate 7%
- Titanium Dioxide 3.5%
- Zinc Oxide 1%

Purpose

Sunscreen

Broad Spectrum SPF 50
Stop the Clock™
Soin Anti-âge Jour SPF 50 50 ml e 1.7 fl oz

www.BIOPELLE.com MADE IN USA/FABRIQUE AUX E-U. 8110054.r2

Peel Here For Drug Facts

Peel Label-Left

Drug Facts (continued)

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

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When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Drug Facts (continued)

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

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 - limit time in the sun, especially from 10 a.m. - 2 p.m.

Peel Label-Right

Drug Facts (continued)

- wear long-sleeve shirts, pants, hats and sunglasses
- children under 6 months: Ask a doctor

Inactive ingredients

water, butylene glycol dicaprylate/dicaprate, c12-15 alkyl benzoate, sodium hyaluronate, hydrolyzed potato protein, gamma aminobutyric acid, decamethylcyclopentasiloxane, polysilicone-15, c18-36 acid triglyceride, hexapeptide-11, silica, dipalmitoyl hydroxyproline, polyacrylate-13, hexanoyl dipeptide-3 norleucine acetate, thermus thermophilus ferment, uncaria tomentosa extract, porphyra umbilicalis extract, sodium tocopheryl phosphate, hydrolyzed vegetable protein, adenosine triphosphate, acetyl tyrosine, proline, sodium stearyl glutamate, ▶

Drug Facts (continued)

dimethicone, dimethiconol, cyclopentasiloxane, lecithin, sodium lactate, triethoxycaprylylsilane, cyclomethicone, peg-10 dimethicone, silica dimethyl silylate, glycerin, polyisobutene, polysorbate 20, phenoxyethanol, caprylyl glycol, butylene glycol, citric acid, xanthan gum, hexylene glycol, disodium edta, methicone, alcohol, eugenol

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avobenzone, homosalate, titanium dioxide, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:42485-006 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 30 mg in 1 mL |
| HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S) | HOMOSALATE | 70 mg in 1 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 35 mg in 1 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 10 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0K00R) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| POTATO (UNII: CFE1S8DYWD) | |
| .GAMMA.-AMINOBUTYRIC ACID (UNII: 2ACZ6IPC6I) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PC10R) | |
| POLYSILICONE-15 (UNII: F8DRP5BB29) | |
| C18-36 ACID TRIGLYCERIDE (UNII: ZRA72DR3R7) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| DIPALMITOYL HYDROXYPROLINE (UNII: E6AHA53N1H) | |
| HEXANOYL DIPEPTIDE-3 NORLEUCINE ACETATE (UNII: P8A02Z93M6) | |
| CAT'S CLAW (UNII: 9060PRM18Q) | |
| PORPHYRA UMBILICALIS (UNII: 14AN0J70WO) | |
| ADENOSINE TRIPHOSPHATE (UNII: 8L70Q75FXE) | |
| N-ACETYL-TYROSINE (UNII: DA8G610ZO5) | |
| PROLINE (UNII: 9DLQ4CIU6V) | |
| SODIUM STEAROYL GLUTAMATE (UNII: 65A9F4P024) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PC10R) | |

| |
|--|
| SODIUM LACTATE (UNII: TU7HW0W0QT) |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) |
| CYCLOMETHICONE (UNII: NMQ347994Z) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) |
| PHENOXYETHANOL (UNII: HE492ZZ3T) |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) |
| XANTHAN GUM (UNII: TTV12P4NEE) |
| HEXYLENE GLYCOL (UNII: KEH0A3F75J) |
| EDETATE DISODIUM (UNII: 7FLD91C86K) |
| ALCOHOL (UNII: 3K9958V90M) |
| EUGENOL (UNII: 3T8H1794QW) |
| POLYISOBUTYLENE (1000 MW) (UNII: 5XB3A63Y52) |
| DIMETHICONOL (41 MPA.S) (UNII: 343C7U75XW) |
| LECITHIN, SOYBEAN (UNII: 1DI56QDM62) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:42485-006-01 | 50 mL in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 08/01/2009 | |

Labeler - Biopelle, Inc. (808158823)

Registrant - Biopelle, Inc. (808158823)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------|---------|-----------|---------------------|
| Biogenesis Inc. | | 069117328 | manufacture |