

SAMHEALTHYSKIN B.B. SUNSCREEN BROAD SPECTRUM SPF 40 - titanium dioxide cream

Samhealthyskin.COM LLC

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.

Samhealthyskin B.B. SUNSCREEN CREAM BROAD SPECTRUM SPF 40

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Active ingredient

Titanium Dioxide 10%

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

For sunscreen use

- 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

WATER, MINERAL OIL, CYCLOMETHICONE, PROPYLENE GLYCOL, DIMETHICONE/PEG-10/15 CROSSPOLYMER, CETYL PEG/PPG-10/1 DIMETHICONE, TALC, IRON OXIDES, HYALURONIC ACID, BEESWAX, MICROCRYSTALLINE WAX, SHEA (BUTYROSPERMUM PARKII) BUTTER, TRIBEHENIN, SORBITAN SESQUIOLEATE, SOLUBLE COLLAGEN, TOCOPHERYL ACETATE, ALLANTOIN, TEA (CAMELLIA SINENSIS) LEAF EXTRACT, WHITE MULBERRY (MORUS ALBA) BARK EXTRACT, LICORICE (GLYCYRRHIZA GLABRA) ROOT EXTRACT, DIPOTASSIUM GLYCYRRHIZATE, ETHYLPARABEN, PROPYLPARABEN, BUTYLPARABEN, DISODIUM EDTA, RED GINSENG (PANAX GINSENG)EXTRACT, SODIUM CHLORIDE, FRAGRANCE

Samhealthskin B.B. SUNSCREEN CREAM BROAD SPECTRUM SPF 40 1.69oz/50ml (57650-159-79)

Drug Facts

| Active ingredient | Purpose |
|----------------------|-----------|
| Titanium Dioxide 10% | Sunscreen |

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Samhealthyskin® supports cancer research



★★★★★

Samhealthyskin®



B.B.

SUNSCREEN CREAM
TITANIUM DIOXIDE
BROAD SPECTRUM SPF 40

1.69 FL OZ (50 ML)

Samhealthyskin®

**B.B. SUNSCREEN CREAM
BROAD SPECTRUM SPF 40**

REAL RED GINSENG AND COLLAGEN

Samhealthyskin Cream utilizes modern technology with ancient herbal know-how that provides brightening, anti-wrinkling, antioxidant, hydration, and broad spectrum sunscreen protection SPF40. It contains a broad spectrum sunscreen ingredient that can decrease early skin aging caused by the sun, if used with other protective measures (see Drug Facts chart). It contains ingredients that are antioxidants and can make skin appear smoother with moisturizers to prevent dry skin. It combines the property of Shea Butter to moisturize the skin to make it appear more firm. It also contains collagen to smoothen the skin.

For more information, pls contact
Toll Free (Domestic US)
Tel: 1-855-448-7688

Manufactured for
Samhealthyskin.com LLC,
San Jose, California, 95116
USA

www.samhealthyskin.com

MADE IN KOREA



SAMHEALTHYSKIN B.B. SUNSCREEN BROAD SPECTRUM SPF 40

titanium dioxide cream

Product Information

| | | | |
|-------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:57650-159 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|--|------------------|----------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 100 mg in 1 mL |
|--|------------------|----------------|

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| CYCLOMETHICONE (UNII: NMQ347994Z) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| POLYETHYLENE GLYCOL 500 (UNII: 761NX2Q08Y) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) | |
| TALC (UNII: 7SEV7J4R1U) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| HYALURONIC ACID (UNII: S270N0TRQY) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| TRIBEHENIN (UNII: 8OC9U7TQZ0) | |
| SORBITAN SESQUIOLEATE (UNII: 0W8RRI5W5A) | |
| MARINE COLLAGEN, SOLUBLE (UNII: 8JC99XGU4W) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALLANTOIN (UNII: 344S277G0Z) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| MORUS ALBA BARK (UNII: 7O71A48NDP) | |
| LICORICE (UNII: 61ZBX54883) | |
| GLYCYRRHIZINATE DIPO TASSIUM (UNII: CA2Y0FE3FX) | |
| METHYL PARABEN (UNII: A2I8C7HI9T) | |
| PROPYL PARABEN (UNII: Z8IX2SC1OH) | |
| BUTYL PARABEN (UNII: 3QPII03FV8) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| ASIAN GINSENG (UNII: CUQ3A77YXI) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:57650-159-79 | 50 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 | 04/25/2013 | |

Labeler - Samhealthyskin.COM LLC (067387798)

Registrant - Samhealthyskin.COM LLC (067387798)

Establishment

| Name | Address | ID/FEI | Business Operations |
|-------------|---------|-----------|------------------------|
| Art Nouveau | | 557796198 | manufacture(57650-159) |

Revised: 8/2015

Samhealthyskin.COM LLC