

LUMINIZING MOISTURE TINT SUNSCREEN BROAD SPECTRUM SPF 20 BRONZED- zinc oxide and titanium dioxide cream

Jouer Cosmetics 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.

Luminizing moisture tint sunscreen broad spectrum SPF 20 "Bronzed"

Unit Carton

PROCEVA NI



50 ml / 1.7 fl. oz.

luminiizing moisture tint sunscreen
BROAD SPECTRUM SPF 20
hydratant illuminateur teinté
OIL FREE • HYPOALLERGENIC • FRAGRANCE FREE

Jouer

For Cosmetic Application: Apply Luminiizing Moisture Tint to clean skin with Jouer Foundation Brush no.6 or fingertips to even out complexion. Layer for additional coverage.

Jouer®

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This lightweight moisture tint helps even out imperfections and enhances skin tone with its light-diffusing Multi-Mineral Complex. SPF 20 protects from UVA and UVB rays while Vitamin E, Ginseng and Ginkgo Biloba Leaf Extract deliver antioxidants to your skin, promoting a healthy natural glow.

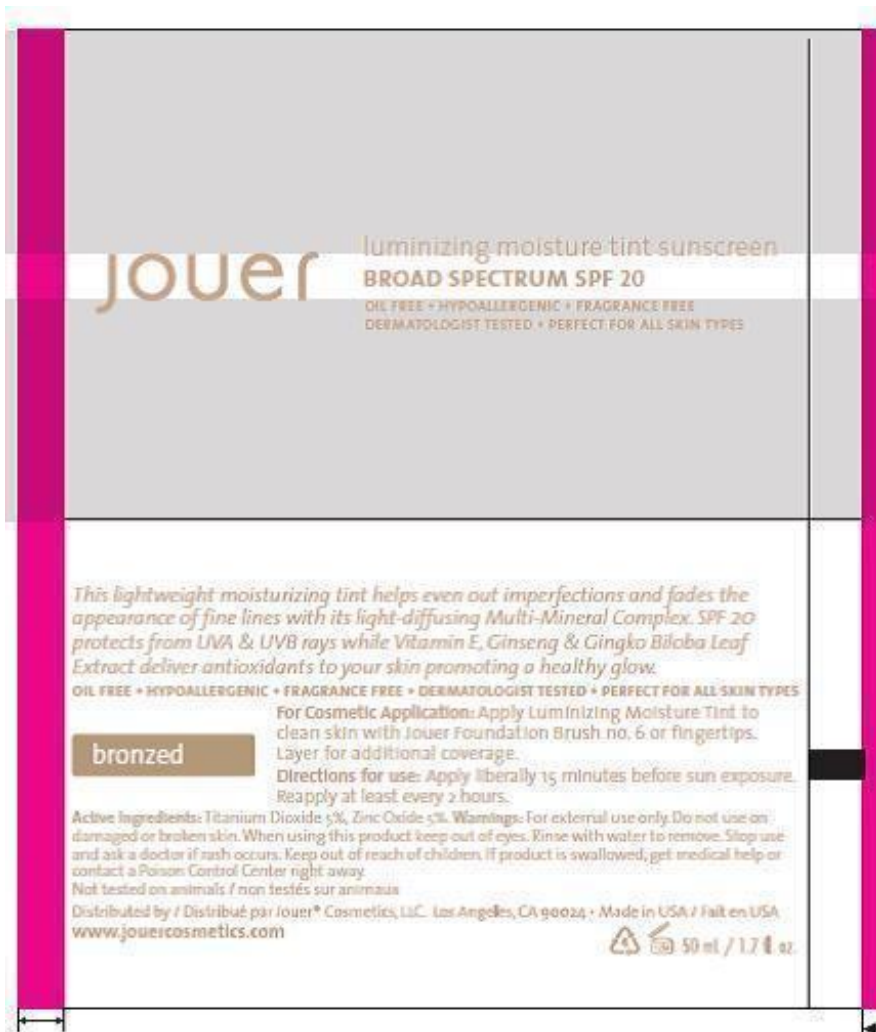
OIL FREE • HYPOALLERGENIC • FRAGRANCE FREE • DERMATOLOGICALLY TESTED • PERFECT FOR ALL SKIN TYPES

luminiizing moisture tint sunscreen

BROAD SPECTRUM SPF 20

| | |
|--|---|
| <p>Drug Facts</p> <p>Active Ingredients</p> <p>Titanium Dioxide, 5% Zinc Oxide, 5%</p> <p>Purpose</p> <p>Sunscreen</p> | <p>Drug Facts (continued)</p> <ul style="list-style-type: none"> • tint time in the sun, especially from 10 a.m. - 2 p.m. • wear long-sleeved shirts, pants, hats, and sunglasses. |
| <p>Uses</p> <ul style="list-style-type: none"> • 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 | <p>Other Information</p> <ul style="list-style-type: none"> • protect the product from excessive heat and direct sun. • you may report a serious adverse reaction to Jouer Customer Support. Toll free: 1-800-615-5374, M-F, 9am - 5pm PST (US & Canada only) |
| <p>Warnings</p> <p>For external use only</p> <p>Do not use on damaged or broken skin</p> <p>When using this product, keep out of eyes. Flush with water to remove.</p> <p>Stop use and ask a doctor if rash occurs</p> <p>Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.</p> | <p>Inactive Ingredients</p> <p>Water, Cyclopentasiloxane, Propylene Glycol, Octyldodecyl Nonylcarbamate, PEG/PPG-18/18 Dimethicone, Dimethicone, Magnesium Chloride, Potassium Chloride, Sodium Chloride, Zinc Chloride, Lysine, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Arbutin, Nobiletin Flower Extract, Camellia Oleifera Leaf Extract, Pyridoxin, Magnesium Ascorbyl Phosphate, Pteroyl-L-phenylalanine, Tocopherol, Tetrahydrofurfuryl Alcohol, Aluminum Hydroxide, Stearic Acid, Triethoxycaprylylsilane, Boron Nitride, Glycerin, Panthoic Acid, Dried Palm Fruit, Sodium Hyaluronate, Glycerin, Glycol, Sodium Dihydroxyacetate, Phenoxyethanol, Methylparaben, Propylparaben, Methylparaben, Iron Oxide (CI 77491, CI 77492, CI 77499), Mica, Titanium Dioxide (CI 77891).</p> |
| <p>Directions</p> <ul style="list-style-type: none"> • apply liberally 15 minutes before sun exposure • use a water resistant sunscreen if swimming or sweating. Immediately after towel drying, reapply at least every 2 hours • children under 6 months: Ask a doctor • Sun Protection Measures: Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease the risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including: | |

Tube



Titanium Dioxide 5%

Zinc Oxide 5%

Sunscreen

Uses

Helps prevent sunburns

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

Warnings

For external use only

Do not use on damages or broken skin

Stop use and ask a doctor if rash occurs

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

Keep out of reach of children. If swallowed, get medical help or contact a poison control center right away

Directions

apply liberally 15 minutes before sun exposure

use a water resistant sunscreen if swimming or sweating: Immediately after towel drying.

reapply at least every 2 hours.

Children under 6 months. Ask a doctor

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 measure including:

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

wear long-sleeved shirts, pants, hats, and sunglasses

protect this product from excessive heat and direct sun.

-you may report a serious adverse reaction to Jouer Customer support, toll free: 1-800-315-5374, M-F, 8am-6pm PST (US and Canada Only)

Water, Cyclopentasiloxane, Propylene Glycol, Octyldodecyl Neopentanoate, PEG/PPG 18/18 Dimethicone, Dimethicone, Magnesium Chloride, Potassium Chloride, Sodium Chloride, Zinc Chloride, Lysine, Panax Ginseng Root Extract, Ginkgo Biloba Leaf Extract, Anthemis Nobilis Flower Extract, Camellia Oleifera Leaf Extract, Phytantriol, Magnesium Ascorbyl Phosphate, Retinyl Palmitate, Tocopheryl Acetate, Tocopherol, Tetrahexyldecyl Ascorbate, Aluminum Hydroxide, Stearic Acid, Triethoxycaprylylsilane, Boron Nitride, Glycerin, Palmitic Acid, Dextrin Palmitate, Sodium Hyaluronate, Butylene Glycol, Sodium Dehydroacetate, Phenoxyethanol, Methylparaben, Propylparaben, Mica, Titanium Dioxide (CI 77891), Iron Oxide (CI 77491, CI77492, CI77499)

LUMINIZING MOISTURE TINT SUNSCREEN BROAD SPECTRUM SPF 20 BRONZED

zinc oxide and titanium dioxide cream

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:69017-302

Route of Administration

TOPICAL

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|--------------------------|------------------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 5.0 mg in 100 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37) | ZINC CATION | 5.0 mg in 100 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| CYCLOMETHICONE 5 (UNII: 0THT5PCI0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| OCTYLDODECYL NEOPENTANOATE (UNII: X8725R883T) | |
| PEG/PPG-18/18 DIMETHICONE (UNII: 9H0AO7T794) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| MAGNESIUM CHLORIDE (UNII: 02F3473H9O) | |
| POTASSIUM CHLORIDE (UNII: 660YQ98I10) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| ZINC CHLORIDE (UNII: 86Q357L16B) | |
| LYSINE (UNII: K3Z4F929H6) | |
| ASIAN GINSENG (UNII: CUQ3A77YXI) | |
| GINKGO (UNII: 19FUJ2C58T) | |
| CHAMAEMELUM NOBILE FLOWER (UNII: O2T154T6OG) | |
| CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60) | |
| PHYTANTRIOL (UNII: 8LVI07A72W) | |
| MAGNESIUM ASCORBYL PHOSPHATE (UNII: 0R822556M5) | |
| VITAMIN A PALMITATE (UNII: 1D1K0N0VVC) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| TOCOPHEROL (UNII: R0ZB2556P8) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| ALUMINUM HYDROXIDE (UNII: 5QB0T2IUN0) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| BORON NITRIDE (UNII: 2U4T60A6YD) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| PALMITIC ACID (UNII: 2V16EO95H1) | |
| ICODextrin (UNII: 2NX48Z0A9G) | |
| SODIUM HYDROXIDE (UNII: 55X04QC32I) | |
| BUTYLENE GLYCOL (UNII: 3XUS85K0RA) | |
| SODIUM DEHYDROACETATE (UNII: 8W46YN971G) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| MICA (UNII: V8A1AW0880) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| FERRIC OXIDE YELLOW (UNII: EX438O2MRT) | |
| FERROSO FERRIC OXIDE (UNII: XM0M87F357) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:69017-302-02 | 1 in 1 BOX | | |
| 1 | NDC:69017-302-01 | 50 mL in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 01/01/2014 | |

Labeler - Jouer Cosmetics LLC (011002088)**Registrant** - Jouer Cosmetics LLC (011002088)

Revised: 12/2014

Jouer Cosmetics LLC