

**JOURNEE BIO-RESTORATIVE DAY BALM BROAD-SPECTRUM SUNSCREEN SPF 30-
octinoxate and zinc oxide lotion
Merz North America, 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.

Journée Bio-restorative Day Balm Broad-spectrum Sunscreen SPF 30

Drug Facts:

Active Ingredients

Octinoxate 7.5%

Zinc Oxide 7.3%

Purpose

Sunscreen

Uses

- Helps prevent sunburn and premature skin aging.
- 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.
- Higher SPF gives more sunburn protection.

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 a Poison Control Center right away.

Directions

- Apply generously 15 minutes before sun exposure.
- Reapply at least every 2 hours.

- Use a water-resistant sunscreen if swimming or sweating.
- For children under 6 months of age, 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 Broad-Spectrum SPF value of 15 or higher and other sun-protection measures including:

- Limit time in the sun, especially from 10am-2pm.
- Wear long-sleeved shirts, pants, hats, and sunglasses.

Inactive Ingredients

Water, Caprylic / Capric Triglyceride, Hydrogenated Poly (C6-14 Olefin), Hexyldecanol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Microcrystalline Cellulose, Camellia Sinensis Leaf Extract, Silica, Cutaneous Lysate, Sodium Ascorbyl Phosphate, Tocopheryl Acetate, Squalane, Hydroxyethyl Acrylate / Sodium Acryloyldimethyl Taurate Copolymer, Polyhydroxystearic Acid, Steareth-21, Melanin, Cetearyl Alcohol, Sodium Hyaluronate, Polysorbate 60, Triethoxycaprylsilane, Disodium EDTA, Xanthan Gum, Styrene / Acrylates Copolymer, Phenoxyethanol, Methylparaben, Ethylparaben, Propylparaben

Other Information

- Protect this product from excessive heat and direct sun.

Distributed in the USA by Merz North America, Inc.
Raleigh, NC 27615

PRINCIPAL DISPLAY PANEL - 200 ML Bottle Label

FOR PROFESSIONAL USE ONLY.
NOT FOR RESALE.

journée

REVITALIZING DAY CREAM
BROAD SPECTRUM
SPF 30

NEOCUTIS®

Boosts collagen to revitalize and hydrate skin, provides anti-oxidant care and broad-spectrum UVA and UVB protection

POWERED BY GROWTH FACTORS

Non-comedogenic, dermatologist-tested, free of color additives and fragrance, not tested on animals

FOR PROFESSIONAL USE ONLY.
NOT FOR RESALE.

| | |
|---|----------------|
| Drug Facts: | |
| Active Ingredients | Purpose |
| Octinoxate 7.5% } Zinc Oxide 7.3% } | Sunscreen |
| Uses | |
| <ul style="list-style-type: none"> • Helps prevent sunburn and premature skin aging. • If used as directed with other sun protection measures (see <i>Directions</i>), decreases the risk of skin cancer and early skin aging caused by the sun. • Higher SPF gives more sunburn protection. | |
| 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 a Poison Control Center right away. | |
| Directions: | |
| <ul style="list-style-type: none"> • Apply generously 15 minutes before sun exposure. • Reapply at least every 2 hours. • Use a water-resistant sunscreen if swimming or sweating. • For children under 6 months of age, 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 Broad-Spectrum SPF value of 15 or higher and other sun-protection measures including: | |
| <ul style="list-style-type: none"> • Limit time in the sun, especially from 10am-2pm. • Wear long-sleeved shirts, pants, hats, and sunglasses. | |
| Inactive Ingredients: | |
| Water, Caprylic / Capric Triglyceride, Hydrogenated Poly (C6-14 Olefin), Hexyldecanol, Glycerin, Glyceryl Stearate, PEG-100 Stearate, Potassium Cetyl Phosphate, Hydrogenated Palm Glycerides, Microcrystalline Cellulose, Camellia Sinensis Leaf Extract, Silica, Cutaneous Lysate, Sodium Ascorbyl Phosphate, Tocopheryl Acetate, Squalane, Hydroxyethyl Acrylate / Sodium Acryloyldimethyl Taurate Copolymer, Polyhydroxystearic Acid, Steareth-21, Melanin, Cetearyl Alcohol, Sodium Hyaluronate, Polysorbate 60, Triethoxycaprylsilane, Disodium EDTA, Xanthan Gum, Styrene / Acrylates Copolymer, Phenoxethanol, Methylparaben, Ethylparaben, Propylparaben | |
| Other Information | |
| • Protect this product from excessive heat and direct sun. | |

journée

REVITALIZING DAY CREAM
BROAD SPECTRUM
SPF 30

NEOCUTIS®

Distributed in the USA by Merz North America, Inc.
Raleigh, NC 27615 | Made in USA

NEOCUTIS.com

USA: 866.636.2884

6.76 FL. OZ. (200 ML)

AW00960-00

JOURNEE BIO-RESTORATIVE DAY BALM BROAD-SPECTRUM SUNSCREEN SPF 30

octinoxate and zinc oxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:46783-002 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|---------------|
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 75 mg in 1 mL |
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 73 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| WATER (UNII: 059QF0KO0R) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K679OBS311) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| ETHYLPARABEN (UNII: 14255EXE39) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| POTASSIUM CETYL PHOSPHATE (UNII: 03KCY6P7UT) | |
| CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S) | |
| GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) | |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) | |
| HEXYLDECANOL (UNII: 151Z7P1317) | |
| STEARETH-21 (UNII: 53J3F32P58) | |
| .ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| HYALURONATE SODIUM (UNII: YSE9PPT4TH) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| SODIUM ASCORBYL PHOSPHATE (UNII: 836SJG51DR) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| MELANIN SYNTHETIC (TYROSINE, PEROXIDE) (UNII: O0CV1RMR44) | |
| BUTYL METHACRYLATE/METHYL METHACRYLATE/METHACRYLIC ACID/STYRENE CROSSPOLYMER (UNII: V5RS026Q0H) | |
| SQUALANE (UNII: GW89575KF9) | |
| POLYSORBATE 60 (UNII: CAL22UVI4M) | |
| HUMAN SKIN PROTEINS, PARTIALLY HYDROLYZED (UNII: G9813R29TW) | |
| HYDROGENATED PALM GLYCERIDES (UNII: YCZ8EM144Q) | |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|--|
| Color | WHITE | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:46783-002-01 | 1 in 1 CARTON | 04/01/2011 | |
| 1 | | 15 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |
| 2 | NDC:46783-002-02 | 1 in 1 CARTON | 04/01/2011 | |
| 3 | | 30 mL in 1 BOTTLE; Type 0: Not a Combination | | |

| | | | | |
|---|------------------|---|------------|------------|
| 2 | | Product | | |
| 3 | NDC:46783-002-03 | 200 mL in 1 BOTTLE; Type 0: Not a Combination Product | 04/01/2011 | |
| 4 | NDC:46783-002-05 | 4 mL in 1 TUBE; Type 0: Not a Combination Product | 04/01/2011 | |
| 5 | NDC:46783-002-50 | 1 in 1 CARTON | 06/18/2019 | 05/31/2024 |
| 5 | | 50 mL in 1 BOTTLE; Type 0: Not a Combination Product | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 04/01/2011 | |

Labeler - Merz North America, Inc. (028147846)

Revised: 1/2023

Merz North America, Inc.