

TINTED ZINC PROTECTION- zinc oxide cream
Teton Dermatology Holdings, Inc.

DRUG FACTS (cont)

INACTIVE INGREDIENTS: Bismuth Oxychloride, C₁₂₋₁₅ Alkyl Benzoate, Caprylhydroxamic Acid, Caprylyl Glycol, Cetyl PEG/PPG 10/1 Dimethicone, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Disodium EDTA, Glycerin, Iron Oxides, Hydrogen Dimethicone, Mica, Microcrystalline Wax, PEG-10 Dimethicone, PEG-30 Dipolyhydroxystearate, Polyglyceryl-4 Isostearate, Polyhydroxystearic Acid, Polysorbate 20, Sodium Chloride, Stearyl Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate, Triethanolamine, Triethoxycaprylylsilane, Water

OTHER INFORMATION:

- Protect this product from excessive heat and direct sun
- May stain some fabrics.

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TETON
DERMATOLOGY
Medical, Surgical & Cosmetic Skin Care

Tinted Zinc Protection
SPF 50
Broad Spectrum

FREE OF CHEMICAL SUNSCREENS

NET WT 2.1 OZ/60 G



DRUG FACTS

ACTIVE INGREDIENTS: Zinc Oxide 20% **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 aging caused by the sun.

WARNINGS: For external use only. Do not use on damaged 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
- Reapply:
 - After 40 minutes of 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 measures including:
 - Limit time in the sun, especially from 10 am- 2 pm
 - Wear long sleeve shirts and hats and sunglasses

TINTED ZINC PROTECTION

zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85339-204(NDC:58892-204) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|---------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 200 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

| |
|--|
| WATER (UNII: 059QF0KO0R) |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) |
| MICA (UNII: V8A1AW0880) |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) |
| EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM) |
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) |
| PEG-30 DIPOLYHYDROXYSTEARATE (UNII: 9713Q0S7FO) |
| CAPRYLHYDROXAMIC ACID (UNII: UPY805K99W) |
| CAPRYLYL GLYCOL (UNII: 00YIU5438U) |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) |
| BISMUTH OXYCHLORIDE (UNII: 4ZR792I587) |
| STEARYL DIMETHICONE (400 MPA.S AT 50C) (UNII: R327X197HY) |
| POLYSORBATE 20 (UNII: 7T1F30V5YH) |
| TRIETHOXYCAPRYLYLSILANE (UNII: LDC331P08E) |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) |
| CI 77491 (UNII: 1K09F3G675) |
| POLYHYDROXYSTEARIC ACID (2300 MW) (UNII: YXH47AOU0F) |
| TRIETHANOLAMINE (UNII: 9O3K93S3TK) |
| CI 77499 (UNII: XM0M87F357) |
| MICROCRYSTALLINE WAX (UNII: XOF597Q3KY) |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) |
| C12-15 ALKYL BENZOATE (UNII: A9EJ3J61HQ) |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 4) (UNII: 8INO2K35FA) |
| DIMETHICONE (UNII: 92RU3N3Y1O) |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) |
| GLYCERIN (UNII: PDC6A3C0OX) |
| CI 77492 (UNII: EX438O2MRT) |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85339-204-60 | 60 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 10/27/2023 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 10/27/2023 | |

Labeler - Teton Dermatology Holdings, Inc. (078310619)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85339-204) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(85339-204) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85339-204) |

Revised: 12/2025

Teton Dermatology Holdings, Inc.