

NON-TINTED PHYSICAL BLOCK SUNSCREEN- titanium dioxide, zinc oxide cream

Tucson Acne Clinic

Active Ingredients:

Titanium Dioxide 8% Zinc Oxide 3.8%

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. 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 the 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 80 minutes of swimming or sweating • Immediately after towel drying • 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-sleeved shirts, pants, hats, and sunglasses

Inactive Ingredients:

Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18 Methicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

Other Information:

- Protect this product from excessive heat and direct sun
- May stain some fabrics
- Cleanse thoroughly at nighttime

- PA+++

Warnings:

Keep out of reach of children

DRUG FACTS (cont)

• 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-sleeved shirts, pants, hats, and sunglasses

INACTIVE INGREDIENTS: Alumina, Cyclohexasiloxane, Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Dimethicone/Vinyl Dimethicone Crosspolymer, Dimethiconol, Lauryl PEG/PPG-18/18-Hydrogen Dimethicone, Hydrogen Dimethicone, PEG-10 Dimethicone, Tetrahexyldecyl Ascorbate, Tocopheryl Acetate

OTHER INFORMATION:

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

Tucson AZ, 85719
tucsonacneclinic.com

**TUCSON
ACNE CLINIC**

**NON-TINTED
PHYSICAL BLOCK
SUNSCREEN**

**ANTIOXIDANTS C & E
SPF 40 BROAD SPECTRUM
WATER RESISTANT (80 MINS)**

NET WT. 1.8 OZ / 53 G

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NON-TINTED PHYSICAL BLOCK SUNSCREEN

titanium dioxide, zinc oxide cream

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:85301-202(NDC:58892-202) |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|--------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 38 mg in 1 g |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 80 mg in 1 g |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| PEG-10 DIMETHICONE (600 CST) (UNII: 8PR7V1SVM0) | |
| DIMETHICONE/VINYL DIMETHICONE CROSSPOLYMER (SOFT PARTICLE) (UNII: 9E4CO0W6C5) | |
| CYCLOHEXASILOXANE (UNII: XHK3U310BA) | |
| DIMETHICONE (UNII: 92RU3N3Y1O) | |
| DIMETHICONE CROSSPOLYMER (UNII: UF7620L1W6) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| ALUMINA (UNII: LMI26O6933) | |
| CYCLOPENTASILOXANE (UNII: 0THT5PCI0R) | |
| LAURYL PEG/PPG-18/18 METHICONE (UNII: ZJ5S27D9NX) | |
| TETRAHEXYLDECYL ASCORBATE (UNII: 9LBV3F07AZ) | |
| DIMETHICONOL (2000 CST) (UNII: T74O12AN6Y) | |
| HYDROGEN DIMETHICONE (20 CST) (UNII: 12Z59IF64N) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:85301-202-50 | 53 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product | 01/22/2024 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 01/22/2024 | |

Labeler - Tucson Acne Clinic (089299711)

Establishment

| Name | Address | ID/FEI | Business Operations |
|----------------------|---------|-----------|---------------------|
| Custom Analytics LLC | | 144949372 | analysis(85301-202) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------------|---------|-----------|------------------------|
| Fragrance Manufacturing Inc. | | 793406000 | manufacture(85301-202) |

Establishment

| Name | Address | ID/FEI | Business Operations |
|-----------------------------|---------|-----------|---------------------|
| Fallien Cosmeceuticals Ltd. | | 958388357 | relabel(85301-202) |