

DERMACINRX SKIN MOISTURIZING ULTRA SPF 50 SUNSCREEN- avobenzone, octinoxate, octisalate, titanium dioxide lotion
PureTek Corporation

Dermacin [®]Rx Skin Moisturizing Ultra SPF 50 Sunscreen Lotion

(avobenzone, octinoxate, octisalate, titanium dioxide)

Active ingredients (% w/w)

Avobenzone 2.5%

Octinoxate 3%

Octisalate 3%

Titanium Dioxide 1.25%

Purposes

Sunscreen (Avobenzone 2.5%)

Sunscreen (Octinoxate 3%)

Sunscreen (Octisalate 3%)

Sunscreen (Titanium Dioxide 1.25%)

Uses

■ Helps prevent sunburn.

■ If used as a directed with other sun protection measures (see Directions), decreases the risk of 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 product is 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 or immediately after towel drying
■ Reapply: ■ at least every 2 hours. ■ 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 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-sleeve shirts, pants, hats, and sunglasses. ■ Children under six months of age: Ask a doctor.

Inactive ingredients

Water, Emulsifying Wax, Shea butter, Stearic Acid, Ethylhexyl Palmitate, Phenoxyethanol, Benzoic Acid, Dehydroacetic Acid, Sunflower Seed Oil, Isopropyl Isostearate, Vitamin E, Potassium Sorbate, Xanthan Gum, Sodium Benzoate.

Other information

■ Protect this product from excessive heat and direct sun

Questions?

1.800.611.4270

Dermacin[®] Rx Skin Moisturizing Ultra SPF 50 Sunscreen Lotion (Label)

DISTRIBUTED BY:

PureTek Corporation
San Fernando, CA 91340

Drug Facts

Active Ingredients: Avobenzone 2.5%, Octinoxate 3%, Octisalate 3%, Titanium Dioxide 1.25%
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 product is 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 or immediately after towel drying. • Reapply • at least every 2 hours. • 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 of 15 or higher and other sun protection measures including: • Limit time in sun, especially from 10 a.m. - 2 p.m. • Wear long-sleeve shirts, pants, hats, and sunglasses. • Children under six months of age: Ask a doctor.

Inactive Ingredients: Water, Emulsifying Wax, Shea Butter, Stearic Acid, Ethylhexyl Palmitate, Phenoxyethanol, Benzoic Acid, Dehydroacetic Acid, Sunflower Seed Oil, Isopropyl Isostearate, Vitamin E, Potassium Sorbate, Xanthan Gum, Sodium Benzoate.

Other Information: • Protect this product from excessive heat and direct sun.

Questions? 1.800.611.4270 **MADE IN THE USA. PABA FREE.**

DISTRIBUTED BY: Puretek Corporation San Fernando, CA 91340

NDC 59088-568-05

DERMACIN[®]R_x

**Skin Moisturizing
Ultra SPF 50 Sunscreen Lotion
PABA Free / Hypo-Allergenic**

Broad Spectrum / Unscented

2.0 fl. oz. (56 mL.) BROAD SPECTRUM SPF 50 Sunscreen Lotion

DERMACINRX SKIN MOISTURIZING ULTRA SPF 50 SUNSCREEN

avobenzone, octinoxate, octisalate, titanium dioxide lotion

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:59088-568 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX) | AVOBENZONE | 25 mg in 1 mL |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 30 mg in 1 mL |
| OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W) | OCTISALATE | 30 mg in 1 mL |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP) | TITANIUM DIOXIDE | 12.5 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| WATER (UNII: 059QF0KO0R) | |
| POLAWAX POLYSORBATE (UNII: Q504PL8E0V) | |
| SHEA BUTTER (UNII: K49155WL9Y) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |
| ETHYLHEXYL PALMITATE (UNII: 2865993309) | |
| PHENOXYETHANOL (UNII: H1E492ZZ3T) | |
| BENZOIC ACID (UNII: 8SKN0B0MIM) | |
| DEHYDROACETIC ACID (UNII: 2KAG279R6R) | |
| SUNFLOWER OIL (UNII: 3W1JG795YI) | |
| ISOPROPYL ISOSTEARATE (UNII: C67IXB9Y7T) | |

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|--|--|
| .ALPHA.-TOCOPHEROL (UNII: H4N855PNZ1) | |
| POTASSIUM SORBATE (UNII: 1VPU26JZZ4) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| SODIUM BENZOATE (UNII: OJ245FE5EU) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:59088-568-05 | 56 mL in 1 BOTTLE; Type 0: Not a Combination Product | 02/16/2017 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M020 | 02/16/2017 | |

Labeler - PureTek Corporation (785961046)

Revised: 10/2024

PureTek Corporation