PURISTICS TOTALLYAGELESS SPF 15 DAILY ANTI-AGING - octisalate, zinc oxide lotion Scerene Healthcare, 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.

puristic[®] totallyageless[®] SPF 15 Daily Anti-Aging Sunscreen Lotion

Drug Facts

Active ingredients

Octisalate 5% Zinc oxide 3.75%

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 the 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 PoisonControlCenter right away.

Directions

- gently smooth over cleansed face and neck daily
- apply liberally 15 minutes before sun exposure
- reapply at least every 2 hours
- use a water resistant sunscreen if swimming or sweating
- 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 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 a.m.-2 p.m.
- wear long-sleeved shirts, pants, hats, and sunglasses

Other information

• protect from excessive heat and direct sun

Inactive ingredients

purified water, caprylic/capric triglyceride (coconut/palm), squalane (olives), glycerin, tapioca starch, sucrose distearate (sugar), sucrose stearate, sunflower seed wax, palm butter, hydrogenated soybean oil, citric acid, lauric acid (coconut), beeswax, rice bran wax, allantoin, rosewood oil, tocopheryl acetate (vitamin E), panthenol (pro-vitamin B5), hyaluronic acid (natural skin conditioner), saccharomyces/hexapeptide-11 ferment extract (natural collagen builder), polylysine (natural preservative), honeysuckle extract (natural preservative)

Principal panel display

new! the power of pure[®]

puris tics [®]

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SPF 15

Daily Anti-Aging

SUNSCREEN LOTION

Broad Spectrum SPF 15

hydrates for younger looking skin

1.7 FL OZ (50 ml)

Pure. Safe. Effective.

naturally preserved & fragrance free

no parabens, phthalates or sulfates

no animal testing

Learn more at www.puristics.com

Puristics Totally Ageless SPF 15 Daily Anti-Aging Sunscreen Lotion is unique because it starts with purity and ends with purity. There are no harmful chemicals, fragrances or toxins added at any step in the process. Powered by a naturally occurring peptide complex, our vitamin enriched product has been proven to be safe *and* effective.

hydrates for younger looking skin

hypoallergenic

free from harmful chemicals

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Actual Size

discover the power of pure

At Puristics, we believe in the Power of Pure - anti-aging skin care products without any potentially harmful chemicals that could seep into your skin. We've created our products using the latest science to unleash the power of naturally derived ingredients, combining them in unique ways to maximize their effectiveness without compromising purity.

Pure. Safe. Effective.



PURISTICS TOTALLYAGELESS SPF 15 DAILY ANTI-AGING

octisalate, zinc oxide lotion

| Product Information | | | |
|---------------------------------|----------------|--------------------|---------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:76026-304 |
| Route of Administration | TOPICAL | | |
| | | | |
| Active Ingredient/Active Moiety | | | |

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-------------------|
| Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W) | Octisalate | 5 mL in 100 mL |
| Zinc Oxide (UNII: SOI2LOH54Z) (Zinc Oxide - UNII:SOI2LOH54Z) | Zinc Oxide | 3.75 mL in 100 mL |

| Ingredient Name | Strength |
|---|----------|
| Water (UNII: 059QF0KO0R) | |
| Medium-chain Triglycerides (UNII: C9H2L21V7U) | |
| Squalane (UNII: GW89575KF9) | |
| Glycerin (UNII: PDC6A3C0OX) | |
| Starch, Tapioca (UNII: 24SC3U704I) | |
| Sucrose Distearate (UNII: 96QS1D0T15) | |
| Sucrose Stearate (UNII: 274KW0O50M) | |
| Helianthus Annuus Seed Wax (UNII: 42DG15CHXV) | |
| Elaeis Guineensis Fruit Butter (UNII: UYH3R74N56) | |
| Hydrogenated Soybean Oil (UNII: A2M91M918C) | |
| Citric Acid Monohydrate (UNII: 2968PHW8QP) | |
| Lauric Acid (UNII: 1160N9NU9U) | |
| Yellow Wax (UNII: 2ZA36H0S2V) | |
| Rice Bran (UNII: R60QEP13IC) | |
| Allantoin (UNII: 344S277G0Z) | |
| Rosewood Oil (UNII: F2522O5L7B) | |
| .alphatocopherol Acetate (UNII: 9E8X80D2L0) | |
| Panthenol (UNII: WV9CM0067Z) | |
| Hyaluronic Acid (UNII: S270N0TRQY) | |
| Lonicera Caprifolium Flower (UNII: 5N1WD9784U) | |

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| # Item Code | Package Description | Marketing Start Date | Marketing End Date |
|--------------------|-------------------------|----------------------|--------------------|
| 1 NDC:76026-304-17 | 1 in 1 BOX | | |
| 1 | 50 mL in 1 BOTTLE, PUMP | | |
| | | | |

| Marketing Information | | | |
|-------------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC monograph not final | part352 | 0 1/0 1/20 12 | |
| | | | |

Labeler - Scerene Healthcare, Inc. (832688209)

| Establishment | | | | |
|----------------------------|---------|-----------|---------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| BioZone Laboratories, Inc. | | 555564293 | MANUFACTURE | |