

ABELLA COLOR SHADE SPF 35 EBONY- octinoxate and zinc oxide lotion
Prime Enterprises 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.

Abella ColorShade Broad Spectrum SPF 35 Tinted Sunscreen Lotion Ebony

Active Ingredients

Octinoxate 3%

Zinc Oxide 3%

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
- reapply:
- after 80 minutes of swimming or sweating
- immediately after towel drying
- 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 this risk, regularly use a sunscreen 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-sleeved shirts, pants, hats, and sunglasses
- children under 6 months: Ask a doctor

Inactive Ingredients

Aloe Barbadensis Leaf Juice, Bentonite, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Cetyl

Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Cholecalciferol, Cyclohexasiloxane, Cyclopentasiloxane, Disodium EDTA, DMDM Hydantoin, Hexyl Laurate, Hydrogenated Castor Oil, Iron Oxides, Isocetyl Stearate, Octyl Stearate, Polyethylene, Polyglyceryl-4 Isostearate, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sodium Chloride, Titanium Dioxide, Tocopheryl Acetate, Triethoxycaprylylsilane, Water

Other Information

- protect this product from excessive heat and direct sun

Questions or comments?

Call toll free 1-877-622-3552

Abella ColorShade SPF 35 Ebony

ColorShade™ SPF 35 Tinted Zinc Oxide Lotion
A multi-functioning tinted sunscreen lotion available in 4 tints, moisturizes and protects the skin. Formulated with Zinc Oxide, Green Tea and Vitamins D & E, this lightweight formula is ideal for all skin types. Hypoallergenic.

Drug Facts

| Active Ingredients | Purpose |
|--------------------------------|-----------|
| Octinoxate 3% Zinc Oxide 3% | 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
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - 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 this 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 6 months. Ask a doctor

Inactive ingredients

Aloe Barbadensis Leaf Juice, Bentonite, Camellia Sinensis (Green Tea) Leaf Extract, Caramel, Cetyl Dimethicone, Cetyl PEG/PPG-10/1 Dimethicone, Cholecalciferol (Vitamin D), Cycloheximide, Disodium EDTA, DMDM Hydantoin, Hexyl Laurate, Hydrogenated Castor Oil, Iron Oxides, Isocetyl Stearate, Melanin, Octyl Stearate, Polyethylene, Polyglyceryl-4 Isostearate, Propylene Glycol, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Silica, Sodium Chloride, Titanium Dioxide, Tocopheryl Acetate (Vitamin E), Water (Aqua)

Other information

- protect this product from excessive heat and direct sun

Questions or Comments?
Call toll free 1-877-622-3552

Distributed by Abella Skin Care, Inc. Boca Raton, FL 33431
www.abellaskincare.com Made in the U.S.A.

ABELLA COLOR SHADE SPF 35 EBONY

octinoxate and zinc oxide lotion

Product Information

| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:58 443-0210 |
|-------------------------|----------------|--------------------|-----------------|
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|-----------------|
| ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z) | ZINC OXIDE | 29.4 mg in 1 mL |
| OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51) | OCTINOXATE | 29.4 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| SODIUM CHLORIDE (UNII: 451W47IQ8X) | |
| ALMOND OIL (UNII: 66YXD4DKO9) | |
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| BENTONITE (UNII: A3N5ZCN45C) | |
| CARAMEL (UNII: T9D99G2B1R) | |
| CETYL DIMETHICONE 45 (UNII: IK315POC44) | |
| CETYL PEG/PPG-10/1 DIMETHICONE (HLB 2) (UNII: V2W71V8T0X) | |
| CHOLECALCIFEROL (UNII: 1C6V77QF41) | |
| HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7) | |
| CYCLOMETHICONE 5 (UNII: 0THF5PCI0R) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| DMDM HYDANTOIN (UNII: BYR0546TOW) | |
| HEXYL LAURATE (UNII: 4CG9F9W01Q) | |
| HYDROGENATED CASTOR OIL (UNII: ZF94AP8MEY) | |
| FERRIC OXIDE RED (UNII: 1K09F3G675) | |
| ISOCETYL STEARATE (UNII: 3RJ7186O9W) | |
| CYCLOMETHICONE 6 (UNII: XHK3U310BA) | |
| WATER (UNII: 059QF0KO0R) | |
| ALOE VERA LEAF (UNII: ZY81Z83H0X) | |
| ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| OCTYL STEARATE (UNII: 772Y4UFC8B) | |
| POLYGLYCERYL-4 ISOSTEARATE (UNII: 820DPX33S7) | |
| TRIETHOXYCAPRYLSILANE (UNII: LDC331P08E) | |

Product Characteristics

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

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:58443-0210-3 | 60 mL in 1 TUBE; Type 0: Not a Combination Product | 11/30/2015 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part352 | 11/30/2015 | |

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

| Name | Address | ID/FEI | Business Operations |
|------------------------|---------|-----------|--|
| Prime Enterprises Inc. | | 101946028 | pack(58443-0210) , manufacture(58443-0210) , label(58443-0210) |

Revised: 1/2020

Prime Enterprises Inc.