

**DERMESSE SUNSCREEN SPF30 MEDIUM TINT- octinoxate, zinc oxide lotion**  
**Axia Medical Solutions, LLC**

*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.*

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**Dermesse Sunscreen SPF30 Tint**

***Active Ingredients***

Octinoxate 7.5% w/w

Zinc Oxide 7% w/w

***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.

**When using this product:**

- Keep out of eyes. Rinse with water to remove.

**Stop use and ask doctor if**

- Rash or irritation develops

**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
  - 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 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***

Water, Cyclomethicone, C12-15 Alkyl Benzoate, C18-38 Alkyl Hydroxystearoyl Stearate, Hexylene Glycol, Aloe Barbadensis Leaf Extract, PEG-40 Stearate, Glycerin, Aluminum Starch Octenylsuccinate, Carnauba Wax, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG100 Stearate, Squalane, Tocopheryl Acetate, Propylene Glycol, Siliconyl Beeswax, Stearoxytrimethylsilane, Green Tea (Camellia Sinensis) Leaf Extract, Glyceryl Dilaurate, Dimethicone, Glyceryl Stearate, Cetearyl Alcohol, Stearyl Alcohol, Steareth-100, Titanium Dioxide, Sorbitan Tristearate, Ceteareth-20, VP/Eicosene Copolymer, Polysorbate-60, Beheneth-5, Triethoxycaprylylsilane, Caprylyl Glycol, Fragrance, Methylisothiazolinone, Iron Oxides: Yellow (C177492), Red (C177491), Black (C177499)

### ***Other information***

*Protect this product from excessive heat and direct sun.*

### ***Questions or Comments?***

866-494-4466 or visit [www.dermesse.com](http://www.dermesse.com)

DERMESSE™

Specially formulated Sunscreen that is ideal for use under all conditions. Enriched with soothing Green Tea and Aloe. Safe for all skin types.



MEDIUM TINT

6 SUNSCREEN SPF30

2 fl.oz. (57mL)

<b>Drug Facts</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Octinoxate 7.5% w/w	Sunscreen
Zinc Oxide 7% w/w	Sunscreen
<b>Uses:</b>	
<ul style="list-style-type: none"> <li>•Helps prevent sunburn</li> <li>•If used as directed with other sun protection measures (see Directions), decreases the risk of skin cancer and early aging caused by the sun.</li> </ul>	
<b>Warnings: For external use only</b>	
<p>Do not use on damaged or broken skin.</p> <p>When using this product:</p> <ul style="list-style-type: none"> <li>•Keep out of eyes. Rinse with water to remove.</li> </ul> <p><b>Stop use and ask doctor if</b></p> <ul style="list-style-type: none"> <li>•Rash or irritation develops</li> </ul> <p><b>Keep out of reach of children</b></p> <ul style="list-style-type: none"> <li>•If swallowed, get medical help or contact a Poison Control Center right away.</li> </ul>	
<b>Directions</b>	
<ul style="list-style-type: none"> <li>•Apply liberally 15 minutes before sun exposure</li> <li>•Reapply                             <ul style="list-style-type: none"> <li>•After 40 minutes of swimming or sweating</li> <li>•Immediately after towel drying</li> <li>•At least every 2 hours</li> </ul> </li> <li>•<b>Sun Protection Measures.</b> Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with broad spectrum SPF of 15 or higher and other sun protection measures including:                             <ul style="list-style-type: none"> <li>•Limit time in the sun, especially from 10 a.m. – 2 p.m.</li> <li>•Wear long sleeve shirts, pants, hats, and sunglasses</li> </ul> </li> <li>•<b>Children under 6 months:</b> Ask a doctor</li> </ul>	
<b>Inactive Ingredients</b>	
Water, Cyclo methicone, C12-15 Alkyl Benzoate, C18-38 Alkyl Hydroxystearoyl Stearate, Hexylene Glycol, Aloe Barbadosis Leaf Extract, PEG-40 Stearate, Glycerin, Aluminum Starch Octenylsuccinate, Camouba Wax, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, PEG100 Stearate, Squalane, Tocopheryl Acetate, Propylene Glycol, Silicoryl Beeswax, Stearoxtrimethylsilane, Green Tea (Camellia Sinensis) Leaf Extract, Glyceryl Dilaurate, Dimethicone, Glyceryl Stearate, Cetearyl Alcohol, Stearyl Alcohol, Steareth-100, Titanium Dioxide, Sorbitan Tristearate, Ceteareth-20, VP Eicosene Copolymer, Polyisobate-60, Beheneth-5, Triethoxycaprylylsilane, Caprylyl Glycol, Fragrance, Methylisothiazolinone, Iron Oxides: Yellow (C177492), Red (C177491), Black (C177499)	
<b>Other information</b>	
Protect this product from excessive heat and direct sun.	
<b>Questions or Comments?</b>	
866-494-4466 or visit <a href="http://www.dermesse.com">www.dermesse.com</a>	

Distributed by: Axis Medical Solutions, Carlsbad, CA 92011

## DERMESSE SUNSCREEN SPF30 MEDIUM TINT

octinoxate, zinc oxide lotion

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:68723-331
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTINOXATE</b> (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	75 mg in 1 g
<b>ZINC OXIDE</b> (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	70 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>CYCLOMETHICONE</b> (UNII: NMQ347994Z)	
<b>ALKYL (C12-15) BENZOATE</b> (UNII: A9EJ3J61HQ)	
<b>HEXYLENE GLYCOL</b> (UNII: KEH0A3F75J)	

<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)
<b>PEG-40 STEARATE</b> (UNII: ECU18C66Q7)
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)
<b>ALUMINUM STARCH OCTENYLSUCCINATE</b> (UNII: I9PJ006294)
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)
<b>HYDROXYETHYL ACRYLATE/SODIUM ACRYLOYLDIMETHYL TAURATE COPOLYMER (100000 MPA.S AT 1.5%)</b> (UNII: 86FQE96TZ4)
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)
<b>SQUALANE</b> (UNII: GW89575KF9)
<b>.ALPHA.-TOCOPHEROL ACETATE</b> (UNII: 9E8X80D2L0)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>BIS-PEG-12 DIMETHICONE (500 MPA.S)</b> (UNII: 2CNS542YRT)
<b>STEAROXYTRIMETHYLSILANE</b> (UNII: 9862TW94B2)
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)
<b>GLYCERYL DILAURATE</b> (UNII: MFL3ZIE8SK)
<b>DIMETHICONE 350</b> (UNII: 2Y53S6ATLU)
<b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)
<b>CETEARYL STEARATE</b> (UNII: 9T97Q8P3CK)
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)
<b>STEARETH-100</b> (UNII: 4OH5W9UM87)
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)
<b>SORBITAN TRISTEARATE</b> (UNII: 6LUM696811)
<b>POLYOXYL 20 CETOSTEARYL ETHER</b> (UNII: YRC528SWUY)
<b>VINYLPYRROLIDONE/EICOSENE COPOLYMER</b> (UNII: 035MV9S1C3)
<b>POLYSORBATE 60</b> (UNII: CAL22UVI4M)
<b>BEHENETH-5</b> (UNII: L4A971L76E)
<b>TRIETHOXYCAPRYLYLSILANE</b> (UNII: LDC331P08E)
<b>CAPRYLYL GLYCOL</b> (UNII: 00YIU5438U)
<b>METHYLISOTHIAZOLINONE</b> (UNII: 229D0E1QFA)
<b>FERRIC OXIDE YELLOW</b> (UNII: EX438O2MRT)
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68723-331-02	57 g in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2015	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	05/01/2015	

**Labeler** - Axia Medical Solutions, LLC (929224694)

Revised: 7/2021

Axia Medical Solutions, LLC