

DERMESSE SUNSCREEN SPF30- octinoxate, titanium dioxide 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.

Dermesse Sunscreen SPF30

Active Ingredients

Octinoxate 7% w/w

Titanium Dioxide 2% w/w

Purpose

Sunscreen

Uses:

- Helps prevent sunburn

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.

Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.

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

Children under 6 months: Ask a doctor

Inactive Ingredients

Water, Aloe Barbadosis Leaf Extract, Isocetyl Stearate, Sorbitol, Cetearyl Alcohol, Ceteareth-20, Tocopheryl Acetate, Acetyl Hexapeptide-8, Hydrolyzed Rice Protein, Alcohol SDA-40, Dimethicone, Octyl Salicylate, Cetyl Alcohol, Methicone, Sodium Laureth Sulfate, Carbomer, Green Tea (Carnellia Sinensis) Leaf Extract, Fragrance, Triethanolamine, Stearic Acid, Lecithin, Alumina, Caprylyl Glycol, Methylisothiazolinone

Other information

Protect this product from excessive heat and direct sun.

Questions or Comments?

866-494-4466 or visit www.dermesse.com



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



Net Wt. 2 oz. (57mL)

6

SUNSCREEN SPF30

Drug Facts	
Active Ingredients	Purpose
Octinoxate 7% w/w	Sunscreen
Titanium Dioxide 2.5% w/w	Sunscreen
Uses:	
•Helps prevent sunburn	
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.	
Skin Cancer/Skin Aging Alert: Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to prevent sunburn, not skin cancer or early skin aging.	
Directions	
• Apply liberally 15 minutes before sun exposure	
• Reapply	
• After 40 minutes of swimming or sweating	
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• Children under 6 months: Ask a doctor	
Inactive Ingredients: Water, Aloe Barbadosis Leaf Extract, Isocetyl Stearate, Sorbitol, Ceteareth-20, Cetearyl Alcohol, Triethoxycaprylylsilane, Tocopheryl Acetate, Acetyl Hexapeptide-8, Hydrolyzed Rice Protein, SD Alcohol 40-B, Dimethicone, Octisalate, Cetyl Alcohol, Sodium Laureth Sulfate, Carbomer, Green Tea (Camellia Sinensis) Leaf Extract, Fragrance, Triethanolamine, Lecithin, Caprylyl Glycol, Methylisothiazolinone.	
Other information	
Protect this product from excessive heat and direct sun.	
Questions or Comments?	
866-494-4466 or visit www.dermesse.com	

Distributed by Axia Medical Solutions 866-494-4466 • Carlsbad, California 92011

DERMESSE SUNSCREEN SPF30

octinoxate, titanium dioxide lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68723-330
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	70 mg in 1 g
TITANIUM DIOXIDE (UNII: 15FIX9V2JP) (TITANIUM DIOXIDE - UNII:15FIX9V2JP)	TITANIUM DIOXIDE	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ISOCETYL STEARATE (UNII: 3RJ7186O9W)	
SORBITOL (UNII: 506T60A25R)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ACETYL HEXAPEPTIDE-8 (UNII: L4EL31FWML)	
ALCOHOL (UNII: 3K9958V90M)	
DIMETHICONE 350 (UNII: 2Y53S6ATLU)	
OCTISALATE (UNII: 4X49Y0596W)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
METHICONE (20 CST) (UNII: 6777U11MKT)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED) (UNII: 59TL3WG5CO)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
TROLAMINE (UNII: 9O3K93S3TK)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
ALUMINUM OXIDE (UNII: LMI26O6933)	
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
METHYLISOTHIAZOLINONE (UNII: 229D0E1QFA)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68723-330-02	57 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part352	04/01/2012	

Labeler - Axia Medical Solutions, LLC (929224694)

Registrant - Axia Medical Solutions, LLC (929224694)

Revised: 7/2021

Axia Medical Solutions, LLC