

**GLIZA BODY MIST SUNSCREEN BROAD SPECTRUM SPF 100- sunscreen spray
EMRA 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.

GLIZA BODY MIST SUNSCREEN BROAD SPECTRUM SPF 100

Active Ingredient(s)

Avobenzone 3%
Homosalate 15%
Octisalate 5%
Octocrylene 10%
Oxybenzone 6%

Purpose

Sunscreen

Use

Uses helps prevent sunburn if used as directed with other sun protection measures decreases the risk of skin cancer and early skin aging caused by the sun.

Warnings

For External Use Only. Flammable, keep away from fire, sparks, and source of ignition. Do not store above 110 oF

When using this product:

Keep out of eyes. In case of contact with eyes, wash thoroughly with water. Avoid contact with broken skin.

Stop use and ask a doctor if irritation and redness develop and persist for more than 72h.

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Centre immediately.

Directions :

Spray liberally and spread evenly by hand 15 minutes before sun exposure apply to all skin exposed to the sun. Reapply after 80 minutes of swimming or sweating, immediately after towel drying. Reapply at least every 2 hours. Children under 6 months of age:

Ask a doctor

Stop use and ask a doctor if irritation or rash occurs. These may be signs of a serious condition.

Inactive ingredients

Ethyl Alcohol, Polyester-7 & Neopentyl Glycol Diheptanoate, Fragrance (Perfume), Glycerine, Aloe Barbadosis Leaf Juice, Propanediol, Tocopherol (Vitamin E) Phenoxylethanol, Ethylhexylglycerin,

Package Label - Principal Display Panel

0.06 L (60 mL) NDC: 77903-002-01

<p>Drug Facts</p> <table border="1"> <thead> <tr> <th>Active Ingredients</th> <th>Purpose</th> </tr> </thead> <tbody> <tr> <td>Avobenzone 3%</td> <td>Sunscreen</td> </tr> <tr> <td>Homosalate 15%</td> <td>Sunscreen</td> </tr> <tr> <td>Octisalate 5%</td> <td>Sunscreen</td> </tr> <tr> <td>Octocrylene 10%</td> <td>Sunscreen</td> </tr> <tr> <td>Oxybenzone 6%</td> <td>Sunscreen</td> </tr> </tbody> </table> <p>Uses helps prevent sunburn if used as directed with other sun protection measures decreases the risk of skin cancer and early skin aging caused by the sun.</p> <p>Warnings For External Use Only. Flammable, keep away from fire, sparks, and source of ignition. Do not store above 110°F When using this product: Keep out of eyes. In case of contact with eyes, flush thoroughly with water. Avoid contact with broken skin. Stop use and ask a doctor if irritation and redness develop and persist for more than 72h. Keep out of reach of children. If swallowed get medical help or contact a Poison Control Centre immediately.</p>	Active Ingredients	Purpose	Avobenzone 3%	Sunscreen	Homosalate 15%	Sunscreen	Octisalate 5%	Sunscreen	Octocrylene 10%	Sunscreen	Oxybenzone 6%	Sunscreen	 <p>GLIZA - CALIFORNIA - <i>Sun Spray</i></p> <p>SPF 100</p> <p>Dermatologically tested</p> <p>Broad Spectrum UVA + UVB Protection Water Resistant (80min)</p> <p>2 fl oz / 60 ml</p>	<p>Directions: Spray liberally and spread evenly by hand 15 minutes before sun exposure apply to all skin exposed to the sun. Reapply after 80 minutes of swimming or sweating, immediately after towel drying. Reapply at least every 2 hours. Children under 6 months of age: Ask a doctor</p> <p>Inactive ingredients: Ethyl Alcohol, Polyester-7 & Neopentyl Glycol Diheptanoate, Fragrance (Perfume), Glycerine, Aloe Barbadosis Leaf Juice, Propanediol, Tocopherol (Vitamin E) Phenoxylethanol, Ethylhexylglycerin, Production Date and Lot Number are on the product. Best before 3 years from the date of production.</p> <p>© 2020 EMRA LLC Newport Beach, CA 92660 USA www.gliza.us</p> <p></p> <p> 896644 1962265</p>
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GLIZA BODY MIST SUNSCREEN BROAD SPECTRUM SPF 100

sunscreen spray

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:77903-002
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	1.8 mg in 60 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	9 mg in 60 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	3 mg in 60 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	6 mg in 60 mL
OXYBENZONE (UNII: 950OS7VE0Y) (OXYBENZONE - UNII:950OS7VE0Y)	OXYBENZONE	3.6 mg in 60 mL

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
POLYESTER (ADIPIC ACID, 1,6-HEXANEDIOL, NEOPENTYL GLYCOL) (UNII: 571593769G)	
FRAGRANCE LAVENDER & CHIA F-153480 (UNII: SXS9CO2TZK)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
PROPANEDIOL (UNII: 5965N8W85T)	
TOCOPHEROL (UNII: R0ZB2556P8)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
2-ETHYLHEXYL GLYCIDYL ETHER (UNII: LU1UZ98B89)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:77903-002-01	60 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/19/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	05/19/2020	

Labeler - EMRA LLC (116584354)

Registrant - EMRA LLC (116584354)

Establishment

Name	Address	ID/FEI	Business Operations
EMRA LLC		116584354	manufacture(77903-002)

Revised: 5/2020

EMRA LLC