

BIOCORNEUM- avobenzene, homosalate, meradimate, octisalate, and octocrylene gel
Biodermis LLC

Biocorneum®

Drug Facts

Active Ingredients	Purpose
Avobenzene 3%	Sunscreen
Homosalate 15%	Sunscreen
Meradimate 5%	Sunscreen
Octisalate 5%	Sunscreen
Octocrylene 10%	Sunscreen

Dosage Form: Gel

Uses

BIOCORNEUM® can reduce the appearance of scars and is ideal for use on any intact skin surface, including skin that flexes (such as joints) and areas exposed to sun (such as the face and hands).

Warnings

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 help prevent sunburn, not skin cancer or early skin aging.**

For external use only.

Keep out of reach of children.

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.

Directions

- Ensure that the affected area is clean and dry.
- Apply a thin, even layer twice daily.
- Allow to dry. Wait 15 minutes before sun exposure.
- Children under 6 months of age: Ask a doctor.

Other Information

Protect product in this container from excessive heat and direct sun.

Inactive Ingredients

Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Silicon Dioxide

Questions?

Call 800.322.3729

PRINCIPAL DISPLAY PANEL - 50 g Tube Carton

BIOCORNEUM®

ADVANCED
SCAR TREATMENT

SILISHIELD®
CROSSLINKED SILICONE
+ BROAD SPECTRUM SPF 30

NET WT 1.73 fl oz (50g)

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BROAD SPECTRUM SPF 30



WATER RESISTANT
(40 Minutes)



FAST DRYING



LIGHTWEIGHT



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CROSSLINKED SILICONE
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NET WT 1.73 fl oz (50g)



BIOCORNEUM® is the only advanced scar treatment with Silishield® crosslinked silicone plus SPF 30 protection.

What is Silishield?

Silishield advances the benefits of traditional silicone sheeting through the comfort and ease of a gel. Crosslinked silicone creates an invisible shield that feels like a second skin and helps reduce the appearance of scars. It can reduce redness and discoloration, soften and flatten new and older hypertrophic and keloid scars resulting from surgical procedures, injuries and burns. The SPF is designed to be effective while also maintaining Silishield's silky-smooth feel and clear appearance.

Manufactured in the USA for:

BIODERMIS LLC
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Henderson, Nevada 89014 USA
800.322.3729 USA
702.260.4466 INTL
www.biodermis.com
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*Data on file



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BIOCORNEUM

avobenzone, homosalate, meradimate, octisalate, and octocrylene gel

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84440-003
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Avobenzone (UNII: G63QQF2NOX) (Avobenzone - UNII:G63QQF2NOX)	Avobenzone	30 mg in 1 g
Homosalate (UNII: V06SV4M95S) (Homosalate - UNII:V06SV4M95S)	Homosalate	150 mg in 1 g
Meradimate (UNII: J9QGD60OUZ) (Meradimate - UNII:J9QGD60OUZ)	Meradimate	50 mg in 1 g
Octisalate (UNII: 4X49Y0596W) (Octisalate - UNII:4X49Y0596W)	Octisalate	50 mg in 1 g
Octocrylene (UNII: 5A68WGF6WM) (Octocrylene - UNII:5A68WGF6WM)	Octocrylene	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CYCLOMETHICONE 5 (UNII: 0THT5PCI0R)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE) (UNII: UF7620L1W6)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:84440-003-10	1 in 1 CARTON	09/01/2024	
1		10 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:84440-003-20	1 in 1 CARTON	09/01/2024	
2		20 g in 1 TUBE; Type 0: Not a Combination Product		
3	NDC:84440-003-50	1 in 1 CARTON	09/01/2024	
3		50 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph drug	M020	09/01/2024	

Labeler - Biodermis LLC (809650005)

Establishment

Name	Address	ID/FEI	Business Operations
Formulated Solutions, LLC		143266687	MANUFACTURE(84440-003)

Revised: 8/2024

Biodermis LLC