

**BIOCORNEUM PLUS BROAD SPECTRUM SPF 30 ADVANCED SCAR TREATMENT GEL- avobenzone,homosalate,meradimate,octisalate,octocrylene gel**  
**Sientra, 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.*

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**Drug Facts**

**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.**

**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.

**Dosage Form**

Gel

**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.

## **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).

## **INACTIVE INGREDIENTS**

Cyclopentasiloxane, Dimethicone, Dimethicone Crosspolymer, Silicon Dioxide

## **PURPOSE**

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).

## **KEEP OUT OF REACH OF CHILDREN.**

Keep out of reach of children.

## **DOSAGE AND ADMINISTRATION SECTION**

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.

## **PRINCIPLE DISPLAY SECTION**

Biocorneum Advanced Scar Treatment Broad Spectrum SPF 30

For Professional Use Only

NET WT 3.35 fl oz (95g)

BIOCORNEUM by Sientra is the only advanced scar treatment with Silishield

patented 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. Patented 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  
Sientra, Inc., Santa Barbara, CA 93117  
2021 Sientra, Inc.  
[sientra.com](http://sientra.com)

BIOCORNEUM and Silishield are registered trademarks of Sientra, Inc.

May be covered by one or more of the following U.S. patents:

5,741,509; 8,021,683; 8,802,133;  
9,339,546; 9,795,706



# BIOCORNEUM PLUS BROAD SPECTRUM SPF 30 ADVANCED SCAR TREATMENT GEL

avobenzone, homosalate, meradimate, octisalate, octocrylene gel

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71241-004
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>OCTOCRYLENE</b> (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
<b>OCTISALATE</b> (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g

<b>MERADIMATE</b> (UNII: J9QGD60OUZ) (MERADIMATE - UNII:J9QGD60OUZ)	MERADIMATE	5 g in 100 g
<b>AVOBENZONE</b> (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	3 g in 100 g
<b>HOMOSALATE</b> (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	15 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
<b>DIMETHICONE CROSSPOLYMER (450000 MPA.S AT 12% IN CYCLOPENTASILOXANE)</b> (UNII: UF7620L1W6)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71241-004-94	1 in 1 CARTON	11/01/2021	
1	NDC:71241-004-95	95 g in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	11/01/2021	

**Labeler** - Sientra, Inc. (010209877)

### Establishment

Name	Address	ID/FEI	Business Operations
FORMULATED SOLUTIONS, LLC		143266687	manufacture(71241-004)

Revised: 9/2021

Sientra, Inc.