BIOCORNEUM PLUS SPF 30 ADVANCED SCAR TREATMENT- octinoxate octisalate octocrylene oxybenzone 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.

DRUG FACTS

Active Ingredients

Active Ingredients	**Purpose**
Octinoxate 7.5%	Sunscreen
Octisalate 5.0%	Sunscreen
Octocrylene 10%	Sunscreen
Oxybenzone 6.0%	Sunscreen

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.

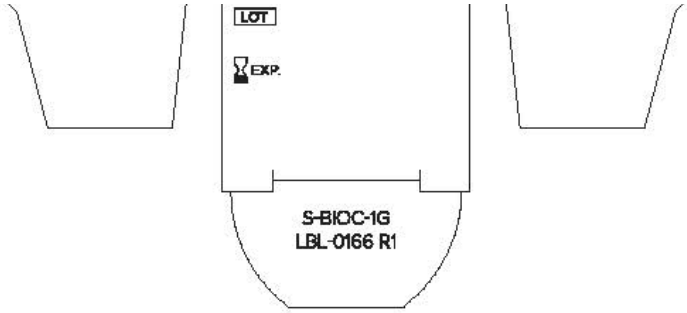
Inactive Ingredients

Isopropyl Myristrate, Polysiloxanes, Silicone Dioxide

Questions?

Call 888.708.0808

Product Package Label



BIOCORNEUM PLUS SPF 30 ADVANCED SCAR TREATMENT

octinoxate octisalate octocrylene oxybenzone gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:71241-001
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
OCTINOXATE (UNII: 4Y5P7MUD51) (OCTINOXATE - UNII:4Y5P7MUD51)	OCTINOXATE	7.5 g in 100 g
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	5 g in 100 g
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	10 g in 100 g
OXYBENZONE (UNII: 95OOS7VE0Y) (OXYBENZONE - UNII:95OOS7VE0Y)	OXYBENZONE	6 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:71241-001-01	1 in 1 CARTON	12/01/2017	
1	NDC:71241-001-96	1 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 final	part352	12/01/2017	

Labeler - SIENTRA, INC. (010209877)