BIOCORNEUM PLUS SPF 30 ADVANCED SCAR SUPERVISION - octinoxate, octisalate, octocrylene, oxybenzone gel
Enaltus 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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bioCorneum + plus SPF 30 advanced SCAR SUPERVISION

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Active ingredients

Octinoxate 7.5%
Octisalate 5.0%
Octocrylene 10%
Oxybenzone 6.0%

Purpose

Sunscreen

Uses

bioCorneumis a unique scar therapy providing a patented silicone gel to help prevent abnormal scar formation with high protection sunscreen agents.

Warnings

For external use only

Keep out of reach of children.

Avoid direct contact with eyes, mucous membranes, third degree burns, and open wounds.

Should not be used on dermatological conditions that disrupt the integrity of the skin.

If irritation occurs, discontinue use and consult your physician.

Directions

Sun Protection Measures. Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:

- limit time in the sun, especially from 10 a.m. - 2 p.m.
- wear long-sleeved shirts, pants, hats and sunglasses
- ensure that the affected area is clean and dry
- apply evenly in a thin layer twice daily, 15 minutes before sun exposure
- allow to dry
- children under 6 months: ask a doctor

Other information

- store below 25ºC (77ºF)

Inactive ingredients

Polysiloxanes, Silicon Dioxide, Isopropyl Myristate

Questions?

1-800-240-8227

Representative Labeling

bioCorneum + plus SPF 30 advanced SCAR SUPERVISION 50g (43474-001-50)
bioCorneum + plus SPF 30 advanced SCAR SUPERVISION 20g (43474-001-20)
bioCorneum + plus SPF 30 advanced SCAR SUPERVISION 10g (43474-001-10)

bioCorneum®+ may reduce redness, soften and flatten scars, and prevent further damage caused by the sun.

Drug Facts

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Manufactured in the USA for:
enaltus™ Suwanee, GA 30024 USA

bioCorneum®+ plus SPF30

advanced
SCAR SUPERVISION

NET WT 50g

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Manufactured in the USA for:
enaltus, LLC Suwanee, GA 30024 USA

www.biocorneumplus.com

US Patents: #5,741,509; #8,263,114; #8,021,683

BCPS50USLB-4

bioCorneum+ plus SPF30

What is bioCorneum++ gel?

bioCorneum++ is an advanced silicone treatment with SPF 30 for minimizing the appearance of scars while protecting them from further damage caused by sun exposure. The gel dries rapidly to form an invisible protective silicone sheet over the affected area. This protective barrier is flexible, waterproof, and breathable. bioCorneum++ forms a bond with the stratum corneum (the outer layer of dead skin cells) to protect the underlying tissue against chemical, physical and microbial invasion of the scar.

Why has my physician recommended I use bioCorneum++ gel?

bioCorneum++ is used for the prevention and management of hypertrophic (raised, red) scars and keloids. It can be used on scars resulting from surgical and cosmetic procedures, trauma, wounds, and burns and is effective on old and new scars.

A new scar will continue to mature for at least 6 months. It has been demonstrated in clinical studies that proactively treating the new scar with the patented silicone formulation in bioCorneum++ may reduce the likelihood of abnormal scar formation and provide the optimal environment for aesthetic scar outcome. Adhering to the twice a day treatment schedule consistently every day, for the prescribed length of treatment, is important. To be effective bioCorneum++ must be in contact with your scar 24 hours a day.

How does bioCorneum++ work?

bioCorneum++ hydrates the scarred area and creates an environment which allows the scar to mature through reduced collagen synthesis cycles and improves the physiological and cosmetic appearance of the scar.

The sunscreen agents in bioCorneum++ protects the maturing scar from the darkening effects of sun exposure, a feature unique to bioCorneum++ as it is the only patented silicone treatment to add such UV protection.

The patented silicone formulation in bioCorneum++ has been shown to flatten, soften, and smooth scars, relieve the itching and discomfort of scars, as well as reduce the discoloration associated with scars.

How is bioCorneum++ different from other scar products?

There are many scar products on the market making big claims to reduce scars. How does a patient know what to believe?

In 2002 the International Clinical Recommendations[1] were published, and in this publication the physician experts in scar treatment gave only one recommendation for topical (non-invasive) treatment for scars: 100% silicone. It has been proven effective in many clinical studies to reduce scars. There was not enough evidence that any other product worked well enough to earn a recommendation.

Plastic Surgeon Massimo Signorini states that in patients studied, the patented silicone formula "is effective in speeding up maturation and reducing the hypertrophy rate of fresh surgical scars" and that it "could currently be the most recommendable agent for scar treatment, especially in visible areas."[2]

Trust your physician. It is your physician's desire that you have the best aesthetic outcome for your scar. Your doctor has recommended bioCorneum++ because he/she is confident that it is the best product to manage your scar.

How should bioCorneum™ be used?

Apply two times daily as directed by physician. Ensure that the affected area is clean and dry. Apply bioCorneum™ to the area in a **very thin layer** and allow to **dry completely**. If the gel has not dried within 5 minutes, you have probably used too much. Gently remove the excess and allow the drying process to continue. Once dry, bioCorneum™ can be covered with pressure garments or cosmetics. If affected area is subject to abrasion, repeated application may be beneficial throughout the day.

For maximum effectiveness, bioCorneum™ should have 24 hour contact with the skin for the duration of treatment. Recommended minimum treatment time for new scars is 60 days. Recommended use for older scars is 90 days. bioCorneum™ is suitable for use on children and people with sensitive skin.

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enaltus™
Suwanee, GA 30024 USA

US Patent Pending 10/480719
International Patents

April 2013 - BCPSUSPI-5

[1]Mustoe TA et al. Plast Reconstructive Surg 2002; 110:560-7
[2]Signorini M et al. Aesth Plast Surg 2007; 31:183-187

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octinoxate, octisalate, octocrylene, oxybenzone gel

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:43474-001
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
ISOPROPYL MYRISTATE (UNII: 0RE8K4LNJS)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:43474-001-50	1 in 1 CARTON		
1		50 g in 1 BOTTLE, PUMP		
2	NDC:43474-001-20	1 in 1 CARTON		
2		20 g in 1 BOTTLE, PUMP		
3	NDC:43474-001-10	1 in 1 CARTON		
3		10 g in 1 BOTTLE, PUMP		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part352	04/10/2014	

Labeler - Enaltus Inc (038868036)

Establishment

Name	Address	ID/FEI	Business Operations
Formulated Solutions, LLC		143266687	manufacture(43474-001)

Revised: 4/2014 Enaltus Inc