BIONECT- dressing, wound and burn, hydrogel w/drug and/or biologic
EPI Health, Inc

BIONECT® Cream
BIONECT® Gel

For topical use only. Rx only.

Product Description

BIONECT Cream is a white, viscous cream. BIONECT Gel is a clear, colorless gel. The principal component is the sodium salt of hyaluronic acid (0.2%). The sodium hyaluronate (Hyalastine®) is derived from a natural fermentation process. Hyaluronic acid is a biological polysaccharide (glycosaminoglycan) and is a major component of the extracellular matrix of connective tissues.

Indications

BIONECT is indicated for the dressing and management of partial to full thickness dermal ulcers (pressure sores, venous stasis ulcers, arterial ulcers, diabetic ulcers), wounds including cuts, abrasions, donor sites, and post-operative incisions, irritations of the skin, and first and second degree burns. The dressing is intended to cover a wound or burn on a patient's skin, and protect against abrasion, friction, and desiccation.

Directions

The wounds or ulcers should be cleaned and disinfected prior to treatment. In the event of long-standing ulcers, it may be advisable to clean and/or to debride the wound by surgical or enzymatic means, prior to treatment. Apply a thin layer of BIONECT without extensive rubbing onto the wound surface, two or three times per day. Cover the lesion area with a sterile gauze pad and, if necessary, with an elastic or compressive bandage.

Warnings

If condition worsens, consult your physician immediately. Keep this product out of the reach of children. The prolonged use of the product may give rise to sensitization phenomena. Should this happen, discontinue the treatment and follow a suitable therapy. Do not use the product after the expiration date reported on the package or if the package is damaged.

Ingredients

BIONECT Cream

Hyaluronic acid sodium salt, polyethylene glycol 400 monostearate, decyl ester of oleic acid, emulsifying wax, glycerol, sorbitol solution 70%, sodium dehydroacetate, methylparaben, propylparaben, fragrance, purified water.

BIONECT Gel

Hyaluronic acid sodium salt, sorbitol solution 70%, sodium dehydroacetate, methylparaben, propylparaben, carbomer 980, sodium hydroxide, purified water.

Contraindications

Do not administer to patients with known hypersensitivity to this product.

Interactions

Do not use concomitantly with disinfectants containing quaternary ammonium salts because hyaluronic acid can precipitate in their presence. The concomitant topical treatment of wounds with antibiotics or other local agents has never given rise to interactions or incompatibilities with BIONECT.

Precautions

Avoid direct contact of container with the affected area. Each container of BIONECT should be used by one patient only in order to reduce the risk of cross infection.

WARNING

Keep out of reach of children.

Adverse Reactions

All suspected adverse reactions occurring during the treatment with BIONECT should be reported to your doctor.

How Supplied

BIONECT Cream/Gel is supplied in a:

25g Cream - 71403-007-02
100g Cream - 71403-007-04
100g Gel - 71403-008-04

Storage

BIONECT Cream may be stored for up to 24 months, BIONECT Gel may be stored for up to 24 months. Store at room temperature below 86°F (30°C).

Manufactured by: Fidia Farmaceutici S.p.A. - Italy

Distributed by: EPI Health, LLC
Charleston, SC 29403
1-800-499-4468
www.epihealth.com
www.Bionect.com

November 2017

Bionect and Hyalastine are registered trademarks of Fidia Farmaceutici S.p.A.

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PRINCIPAL DISPLAY PANEL - 100 g Tube Carton - Cream

71403-007-04

Rx Only
For Topical Use Only

Bionect®
(hyaluronic acid sodium salt, 0.2%) Cream

Net Wt 100g

PRINCIPAL DISPLAY PANEL - 100 g Tube Carton - Gel

71403-008-04

Rx Only
For Topical Use Only

Bionect®
(hyaluronic acid sodium salt, 0.2%) Gel

Net Wt 100g

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Product Information			
Product Type	PRESCRIPTION MEDICAL DEVICE	**Item Code (Source)**	NHRIC:71403-007
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
Hyaluronate sodium (UNII: YSE9PPT4TH) (Hyaluronic acid - UNII:S270N0TRQY)	Hyaluronate sodium	0.2 g in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
polyethylene glycol, unspecified (UNII: 3WJQ0SDW1A)	
decyl oleate (UNII: ZGR06DO97T)	
white wax (UNII: 7G1J5DA97F)	
glycerin (UNII: PDC6A3C0OX)	
sorbitol (UNII: 506T60A25R)	
sodium dehydroacetate (UNII: 8W46YN971G)	

methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71403-007-04	1 in 1 CARTON		
1		100 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:71403-007-02	1 in 1 CARTON		
2		25 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
Premarket Notification	K963004	02/15/2018	

BIONECT

dressing, wound and burn, hydrogel w/drug and/or biologic

Product Information			
Product Type	PRESCRIPTION MEDICAL DEVICE	**Item Code (Source)**	NHRIC:71403-008
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
Hyaluronate sodium (UNII: YSE9PPT4TH) (Hyaluronic acid - UNII:S270N0TRQY)	Hyaluronate sodium	0.2 g in 1 g

Inactive Ingredients	
Ingredient Name	Strength
sodium dehydroacetate (UNII: 8W46YN971G)	
methylparaben (UNII: A2I8C7HI9T)	
propylparaben (UNII: Z8IX2SC1OH)	
Carbomer homopolymer type c (allyl pentaerythritol crosslinked) (UNII: 4Q93RCW27E)	
Sodium hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:71403-008-04	1 in 1 CARTON		
1		100 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
Premarket Notification	K973725	03/01/2018	

Labeler - EPI Health, Inc (080638894)

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