

**BIONECT- dressing, wound and burn, hydrogel w/drug and/or biologic  
Innocutis Holdings LLC**

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**Bionect Cream (Hyaluronic Acid Sodium Salt 0.2%)**

**Description**

Bionect Cream is a white Viscous cream. The principal component is the sodium salt of hyaluronic acid (0.02%). Hyaluronic acid is a biological polysaccharide (glycosaminoglycan) and is a major component of the extracellular matrix of the 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 the 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.

**Warning**

If conditions worsen, 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 expiration date reported on the package.

**Ingredients**

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

**Contraindication**

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

**Drug 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**

Each tube of Bionect should be used by one patient only in order to reduce the risk of cross infection.

### **Adverse Reactions**

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

### **How Supplied**

Bionect Cream is supplied in a:

25g cream Tube - NHRIC 68712-0007-02

50g Cream Tube - NHRIC 68712-0007-03

60g Cream Tube - NHRIC 68712-0007-04

Manufactured for: Inncoutis Holdings LLC, Charleston SC 29401

1-800-499-4468 [www.Innocutis.com](http://www.Innocutis.com), [www.Bionect.com](http://www.Bionect.com)

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

U.S. Pat. No.: 5,925,626

### **Storage**

Please store Bionect at room temperature. Bionect Cream may be stored for up to 24 months.

### **Carton**



## BIONECT

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### Product Information

<b>Product Type</b>	PRESCRIPTION MEDICAL DEVICE	<b>Item Code (Source)</b>	NHRC:68712-007
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### Inactive Ingredients

Ingredient Name	Strength
HYALURONIC ACID (UNII: S270N0TRQY)	.2 g in 1 g
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
DECYL OLEATE (UNII: ZGR06DO97T)	
WHITE WAX (UNII: 7G1J5DA97F)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
SORBITOL (UNII: 506T60A25R)	

<b>SODIUM DEHYDRO ACETATE</b> (UNII: 8W46YN971G)	
<b>METHYL PARABEN</b> (UNII: A2I8C7HI9T)	
<b>PROPYL PARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:68712-007-01	3 g in 1 TUBE		
2	NHRIC:68712-007-02	25 g in 1 TUBE		
3	NHRIC:68712-007-03	50 g in 1 TUBE		
4	NHRIC:68712-007-04	100 g in 1 PACKAGE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K963004	04/01/2004	

**Labeler** - Innocutis Holdings LLC (451549861)

Revised: 9/2012

Innocutis Holdings LLC