

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

Bionect Foam (hyaluronic acid sodium salt, 0.2%)

Description:

Bionect Foam is a soft white foam, which, at rest, takes the form of a clear, pale yellow liquid. 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 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 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 conditions 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 expiration date reported on the package.

Ingredients:

Hyaluronic acid sodium salt, purified water, butane, propylene glycol, polysorbate 80, polyvinylpyrrolidone, propane, methylparaben, sodium dehydroacetate, propylparaben.

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

Bionect Foam - contents under pressure, do not puncture or incinerate. Do not store at temperatures above 120F. Protect from freezing. Keep out of reach of children

Adverse Reactions:

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

How Supplied:

Bionect Foam is supplied in a 113.4g can - 68712-046-01

Storage:

Please store Bionect at room temperature. Bionect Foam may be stored for up to 24 months under these conditions. Store at room temperature below 86F (30C).

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

Distributed by: Innocutis Holdings, LLC

Charleston SC 29401

800-499-4468

www.innocutis.com

www.bionect.com

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

Packaging:

68712-046-01



Distributed by:
Innocutis Holdings, LLC
Charleston, SC 29401
1-800-499-4468
www.innocutis.com

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Bionect is a registered trademark of
Fidia Farmaceutici S.p.A.

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Bionect®
(hyaluronic acid sodium salt, 0.2%) **FOAM**

68712-046-01

Bionect®
(hyaluronic acid sodium salt, 0.2%) **FOAM**

Bionect®

Each 100g of Bionect® Foam contains hyaluronic acid sodium salt 200mg, purified water, butane, propylene glycol, polysorbate 80, polyvinylpyrrolidone, propane, methylparaben, sodium dehydroacetate, propylparaben.

Dosage and Administration:

Apply Bionect® to affected area 2 to 3 times daily or as directed by your physician. See package insert for more information.



Turn can upside down. Firmly push back nozzle until seal is broken. Maintain foam nozzle in a downward position when pushing the nozzle to dispense. Not all liquid will fully dispense from can.

WARNING: for external use only. Keep out of reach of children. Contents under pressure, do not puncture or incinerate. Do not store at temperatures above 120°F. Protect from freezing.

Store at room temperature below 86°F (30°C).

Rx Only
For Topical Use Only
Net Wt 113.4g

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Product Information

Product Type	PRESCRIPTION MEDICAL DEVICE	Item Code (Source)	NHRIC:68712-046
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Inactive Ingredients

Ingredient Name	Strength
HYALURONIC ACID (UNII: S270N0TRQY)	0.2
WATER (UNII: 059QF0KO0R)	
BUTANE (UNII: 6LV4FOR43R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
POVIDONE (UNII: FZ989GH94E)	
PROPANE (UNII: T75W9911L6)	
METHYLPARABEN (UNII: A218C7HI9T)	
SODIUM DEHYDRO ACETATE (UNII: 8W46YN971G)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:68712-046-01	1 in 1 CAN		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K973722	09/08/2014	

Labeler - Innocutis Holdings LLC (451549861)

Revised: 9/2014

Innocutis Holdings LLC