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

Bionect Gel (hyaluronic acid sodium salt, 0.2%)

Description:

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 matric 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, 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

Bionect Gel - 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 Gel is supplied in a 30g tube 68712-008-02, 60g tube 68712-008-03 and 100g tube 68712-008-04

Storage:

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

Manufactured by: 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:

BIONECT GEL

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

Product Information			
Product Type	PRESCRIPTION MEDICAL DEVICE	**Item Code (Source)**	NHRIC:68712-008

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SORBITOL (UNII: 506T60A25R)	
SODIUM DEHYDROACETATE (UNII: 8W46YN971G)	
CARBOMER 940 (UNII: 4Q93RCW27E)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Other Ingredients

Ingredient Kind	Ingredient Name	Quantity
INGR	**HYALURONIC ACID** (UNII: S270N0TRQY)	0.2 in 1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:68712-008-01	3 g in 1 TUBE		
2	NHRIC:68712-008-02	30 g in 1 TUBE		
3	NHRIC:68712-008-03	60 g in 1 TUBE		
4	NHRIC:68712-008-04	100 g in 1 TUBE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
premarket notification	K973725	04/30/2006	

Labeler - Innocutis Holdings LLC (451549861)

Revised: 10/2014 Innocutis Holdings LLC