

Bionect®

(hyaluronic acid sodium salt, 0.2%)

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%). 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.

Ingredients:

BIONECT® Cream - Hyaluronic acid sodium salt (Hyalastine®), polyethyleneglycol 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: 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/Gel is supplied in a:

25g tube (Cream) - NDC 68712-007-02

30g tube (Gel) - NDC 68712-008-02

60g (2 - 30g Gel tubes) - NDC 68712-008-03

Storage: Please store BIONECT® at room temperature. BIONECT® Cream may be stored for up to 24 months, BIONECT® Gel may be stored for up to 24 months.

Manufactured for:

JSJ Pharmaceuticals, Inc.
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www.jsjpharm.com

www.Bionect.com

Manufactured by:

Fidia Farmaceutici S.p.A.
Italy

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

July 2008