

PRODUCT DESCRIPTION

HYALO4 SKIN Cream is a topical preparation constituted by hyaluronic acid as its principal component. Hyaluronic acid is a biological polysaccharide (glycosaminoglycan) distributed in the extracellular matrix of most tissues. Due to its hydrophilic properties it provides hydrated space around and between cells, thus facilitating the migration of cells. HYALO4 SKIN is available in different forms (HYALO4 SKIN Cream, Gauze-pads, Spray and Gel)

Composition

Principal component: Hyaluronic acid sodium salt at 0.2%

Other components: Polyethylenglycol 400 monostearate, Decyl ester of oleic acid, Emulsifying wax, Glycerol, Sorbitol solution 70%, Sodium dehydroacetate, Methyl p-hydroxybenzoate, Propyl p-hydroxybenxoate, Fragrance, Purified water.

Indications

HYALO4 SKIN Cream is indicated for the management of cutaneous irritations and lesions. In particular, it is intended to cover acute and chronic wounds (abrasions, donor sites and post-operative incisions, first and second degree burns, vascular and metabolic ulcers and pressure sores) and to provide a moist wound environment, thus protecting against abrasion, friction and desiccation.

Dosage and Administration

The wounds or ulcers should be cleaned and disinfected prior to treatment. Apply a thin layer of cream onto the wound surface, two or more times a day. The treated area should be covered with a sterile gauze-pad and a sterile bandage.

Contraindications

Do not administer to patients with ascertained individual hypersensitivity to the product components.

Warnings and Precautions

Do not use in case of package damage.

Do not use the product after the expiry date reported on the package.

The expiry date refers to the product kept in its original package at a temperature below 30°C.

Discard after 12 months from the first opening.

Avoid direct contact of the container with the wound.

Each tube of HYALO4 SKIN Cream should be used by one patient only in order to reduce the risk of cross infection. After use, dispose according to applicable national practice.

Keep out of reach of children.

Adverse reactions

The following local adverse reactions may occasionally occur: application site rash, itching, burning sensation, skin irritation, dryness, erythema, dermatitis, skin discoloration. The symptoms are usually transient, of mild severity and rarely require early termination of treatment.

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 HYALO4 SKIN Cream.

Storage

Store below 30°C.

Presentation

Cardboard box containing one 25 g tube Cardboard box containing one 100 g tube

Manufacturer

Fidia Farmaceutici S.p.A. Via Ponte della Fabbrica 3/A 35031 Abano Terme (Padua) İtalya

Importer

PharmaVital İlaç Sağlık Hizmetleri ve Ürünleri İthalat İhracat Sanayi Ticaret Limited Şirketi Barbaros Mh. Al Zambak Sk. Varyap Meridian A Blok Grand Tower No:2 Kat: 8 D: 86 Ataşehir - İstanbul Tel: 0 216 504 07 55

Date of the latest revision of the instructions for use: August 2017

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