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HYALO⁴ 
Plus Cream  0459

PRODUCT DESCRIPTION

HYALO4 Plus Cream is a topical preparation constituted by hyaluronic acid sodium salt as its principal component. Hyaluronic acid is a biological polysaccharide (glycosaminoglycan) distributed in the extracellular matrix of most tissues. Several studies have documented that it may participate in many and diverse tissue repair processes facilitating healing and re-epithelialization. Due to its hydrophilic properties it provides a moist wound environment necessary to the natural healing process. Silver sulfadiazine is a well known anti microbial agent inhibiting the growth in vitro of nearly all pathogenic bacteria and fungi. The presence of silver sulfadiazine in the product composition plays a role in preventing the microbial contamination, thus improving the hyaluronic acid ability to support wound healing. These characteristics allow to change the dressing even only once a day: this causes the minimum discomfort to the patient and the minimum exposure of the lesion to the air, thus reducing the possibility of wound contamination.

Composition

Principal component: Hyaluronic acid sodium salt 0.2%

Other components: Silver Sulfadiazine 1%,

Polyethylenglycol 400 monostearate, Decyl ester of oleic acid, Emulsifying wax, Glycerol, Sorbitol solution 70%, Purified water.

Indications

HYALO4 Plus is indicated for the management of skin lesions, especially those at high risk of infection. In particular, it is intended to cover acute and chronic wounds (first and second degree burns, vascular and metabolic ulcers and pressure sores) and to provide a moist microbe-free wound environment. HYALO4 Plus can be used on non-infected wounds to help in preventing infection and, following successful treatment of infected wounds, to help prevent the reoccurrence of infection.

Dosage and Administration

The lesions should be cleansed prior to each application. Apply a thin layer of cream onto the wound surface, once or twice a day depending on the severity, until complete healing occurs. Prolonged treatments, over a month, should be assessed by a physician on the basis of the clinical evolution of the lesion. The treated area should be covered with a sterile bandage.

Contraindications

Do not administer to patients with ascertained individual hypersensitivity to the product components or with liver or renal failure or glucose-6-phosphate dehydrogenase deficiency. Do not administer to pregnant women and to babies.

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.

After use, dispose according to applicable national practice.

Keep out of reach of children.

Avoid direct contact of the container with the wound.

Each tube of HYALO4 Plus Cream should be used by one patient only, in order to reduce the risk of cross infection.

Avoid exposing treated areas to sunlight, as products containing silver sulfadiazine may stain skin brownish grey. Any staining can easily be removed by washing the area, however.

Interactions

Do not use concomitantly with disinfectants containing quaternary ammonium salts or with locally applied proteolytic enzymes, because they can interact with the product.

Undesirable effects

HYALO4 Plus is usually well tolerated. When extensive areas of the body are treated, the side effects that are sometimes observed after systemic administration of sulfonamides may occur, such as renal failure, toxic hepatitis, agranulocytosis, thrombocytopenia, leukopenia.

Storage

Store at a temperature below 30 °C

Do not freeze.

How supplied

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: September 2017



Consult instructions for use



Use by



Batch number



Temperature limitation



Months after the first opening



Do not use in case of package damage.



Manufacturer