



**fidia**  
farmaceutici

Fidia Farmaceutici S.p.A. - [www.fidiapharma.com](http://www.fidiapharma.com)

**HYALO<sup>4</sup>**  0373  
**Start**

## INSTRUCTIONS FOR USE

### Description of the product

HYALO4 START is a fluid ointment for topical use containing sodium hyaluronate obtained by bacterial fermentation, as the principal component, and bacterial collagenase obtained from a non-pathogenic *Vibrio alginolyticus* strain, as an incorporated medicinal substance.

HYALO4 START allows the preparation of the wound bed, thanks to the hydrating properties of hyaluronic acid that promotes the natural repair process and protects the new viable tissue. In fact the process of cicatrization of the lesions takes place more rapidly in a moist environment. The bacterial collagenase assists in the wound bed preparation.

### Composition

Principal component: sodium hyaluronate 0.2%

Other components: collagenase (not less than 2.0 nkat/g of ointment<sup>1</sup>), light liquid paraffin, white petrolatum.

### Indications

Local management of chronic ulcers (i.e. pressure sores, vascular ulcers of the legs, diabetic ulcers). In particular, it is intended to provide an optimal moist environment and wound bed preparation that supports the natural healing process.

### Dosage and mode of administration

The wounds should be cleaned and disinfected before the application. A sufficient humidity in the area of the lesion must be present to assure a successful treatment. Dry lesions must be moistened with physiological solution (0.9% NaCl) or with solutions well tolerated by the tissue, as the glucose solution. Hard eschars should be softened by applying a wet dressing.

Apply a layer of about 2 mm of HYALO4 START on the wound once a day or as per your doctor's advice. Cover the treated area with a sterile dressing to assure an appropriate contact.

### Pregnancy and Lactation

HYALO4 START can be used during pregnancy and lactation, if indicated by physician.

### Contraindications

Patients with ascertained individual hypersensitivity to the product components must not use HYALO4 START.

### Warnings and precautions

It is suggested not to use the product for a period longer than 30 days.

Consult your physician in case of infection complication. Tetracycline should not be used locally with HYALO4 START.

Do not use the product concomitantly with soaps/ detergents, disinfectants containing quaternary ammonium salts, silver and other heavy metals, which can reduce the action of the product. Ask your physician the possible products to be used.

Do not use on exposed cartilage or tendons. Avoid contact with eyes and mucosae.

In case of accidental ingestion or inhalation consult the physician immediately.

Avoid the direct contact of the container with the wound.

After each application put the cap back on the container.

Do not use in case of package damage.

The product can be used up to 36 months after the first opening of the tube.

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

The expiry date refers to the product stored correctly.  
After use, dispose according to applicable national regulations.  
Keep out of sight and reach of children.

#### **Undesiderable effects**

Undesiderable local effects such as pain, itching, burning and erythema may occur. Undesirable effects of systemic type cannot be excluded in patients with ascertained hypersensitivity towards the components of the product.

#### **Storage**

Store at temperature not exceeding 30 °C.  
Do not freeze.

#### **Presentation**

Tube of 30g.

#### **Manufacturer**

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

#### **Importer**

PharmaVital İlaç Sağlık Hizmetleri ve Ürünleri İthalat ve 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**

<sup>1</sup>The katal (symbol: kat) is the SI unit of catalytic activity.  
[Nomenclature Committee of the International Union of Biochemistry (NC-IUB) (1979).]



Consult instructions for use



Use by



Batch number



Temperature limitation



Do not use in case of package damage.



Manufacturer