fidia

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

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www.fidiapharma.com

Versione/*Version:* **2**
Data Rev./*Rev. date:* **17.07.2024**

Prodotto/*Product name:* **Istr. Hyalgan Sir. Indonesia**

Codice/*Item:*	Revisione/*Revision:*	Data/*Date:*
683946	**D**	**08.07.2024**

Disegno No./*Master No.:* **013**	Fustella/*Die Cut:* **N/A**
Dimensioni/*Size:* (in mm) **139 x 180**	Tecnica di Stampa/*Print Process:* **Offset**
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Interlinea/*Leading:* **11 pt**	Scala Orizzontale/*Horizontal Scale:* **100%**

Braille:	Pharmacode No:	Edge Code:
No	**Laetus**	**11/F/Black • 25/F/Black**

Motivo della modifica/*Change Description:* **Changed old logo Fidia**

Colori/*Colors No:* **1**

Black

Vernici/*Varnish No:* **N/A**

Artwork Operator

Alessandro Marchi
A.O Signature

Notes

D.A.R Signature for approval

Oriz_IND • Version 3.1/01.2024

180 mm Barra di Misurazione / Measuring Bar

Hyalgan®

Hyaluronic acid sodium salt

COMPOSITION
Each mL contains:
Active ingredient: Hyaluronic acid sodium salt (Hyalectin®) 10 mg
Excipients: Sodium chloride 8.5 mg, Monobasic sodium phosphate dihydrate 0.05 mg, Dibasic sodium phosphate dodecahydrate 0.6 mg, Water for injections q.s. to add 1 mL.

MODE OF ACTION
Hyaluronic acid is the prototype of a wide range of saccharide biopolymers (glycosaminoglycans of mucopolysaccharides) which are important components of all extracellular matrices, including cartilage and synovial fluid.

The active ingredient in the speciality HYALGAN® is specific hyaluronic acid fraction with a high degree of molecular definition and purity, isolated from cock's combs.

The introduction of this biological substance into joints with degenerating cartilage surfaces and pathologically altered synovial fluid results in improved joint function, thanks to the normalization of synovial fluid quality and the activation of tissue repair processes in articular cartilage.

INDICATIONS
Degenerative joint disease. Adjuvant in orthopaedic surgery.

DOSAGE AND ADMINISTRATION
Degenerative joint disease and adjuvant in orthopaedic surgery: According to joint size 2 mL or less are administered intra-articularly once a week. Treatment schedules tried so far have included up to 6 weekly injections.
More than one joint may be treated at the same time.

WARNINGS AND PRECAUTIONS
It is necessary to follow a correct technique of intra-articular injection in accurately aseptic conditions, taking care not to cause tissue damage in the injection path.
Should be used with care in the presence of infections, because of the danger of spreading the infections, it should not be injected in or around an infected area.
Malignancy may similarly be a contra-indication.
Should not be given intravenously.

Codice Laetus N° 810 / Codice N° 936

Signature for approval

Trademark

Marketing

D.A.R.

DISETUJUI OLEH BPOM : 03/11/2025

ID : EREG100217VR12500199

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180 mm Barra di Misurazione / Measuring Bar

SIDE EFFECTS
Joint swelling and / or local pain may occur after intra-articular injection into a minority of patients. Such symptoms are transient and will disappear in a few hours.

Hypersensitivity may occur occasionally.

CONTRAINDICATIONS
There are not known contra-indications to the intra-articular supply of exogenous hyaluronic acid.

INTERACTIONS
Administration of salicylates antagonizes the action of hyaluronidase.

STORAGE
Do not use Hyalgan® if package is opened or damaged. Store in original packaging in temperature (protected from light) not exceeding 25°C.

PACKAGE
Box of 1 pre-filled syringe 2 mL for intra-articular use
Reg. No. DKI9576600343A2

The expiry date reported on the package refers to the product stored correctly in its original package.
Warnings: do not use the product after the expiry date reported on the package.

HARUS DENGAN RESEP DOKTER
KEEP OUT OF REACH OF CHILDREN

Manufactured by:
Fidia Farmaceutici S.p.A.,
Abano Terme, Italy

Imported and repacked by:
PT Combiphar
Bandung, Indonesia

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