

NEOIAL HC

The innovation of the **HYALURONIC ACID**
with **SILKWORM COLLAGEN**



NEOIAL HC

STERILE HYDROGEL, TRANSPARENT, VISCOELASTIC, ADSORBABLE

Based on HIGHLY PURIFIED HYALURONATIC SODIUM
with TWO MOLECULAR WEIGHTS and
SILKWORM RECOMBINANT COLLAGEN



40 mg in 2 ml



60 mg in 4 ml



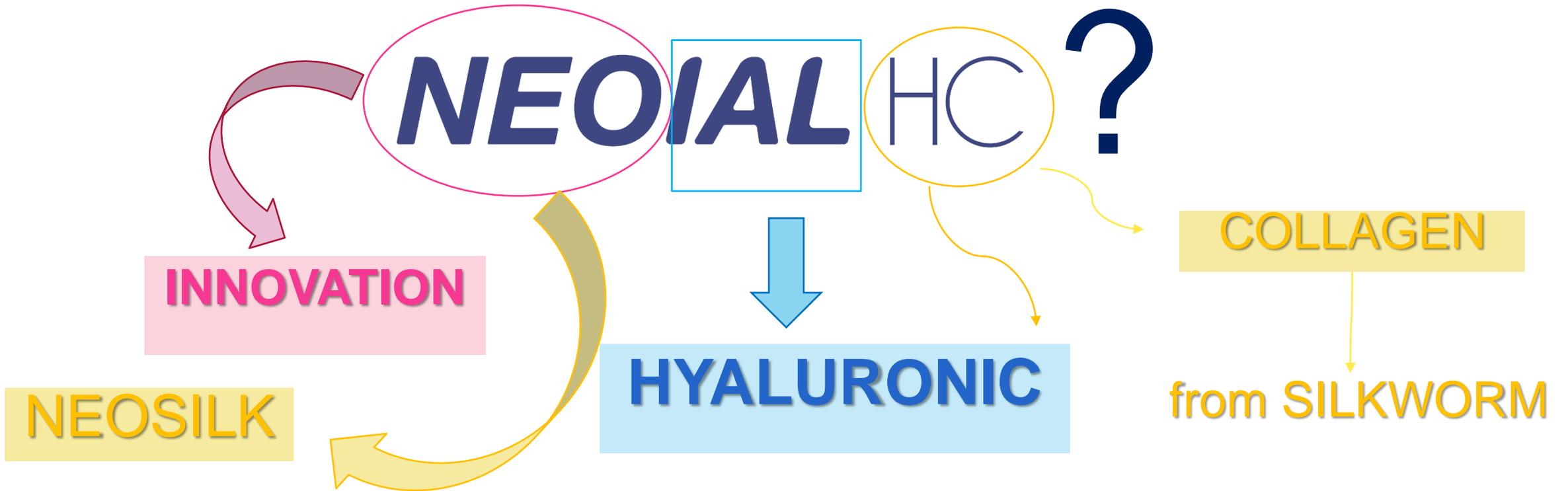
80 mg in 4 ml

NEOIAL HC

Class III MEDICAL DEVICE for INTRA-ARTICULAR USE
*certified by the Notified Body with the **CE 0477***

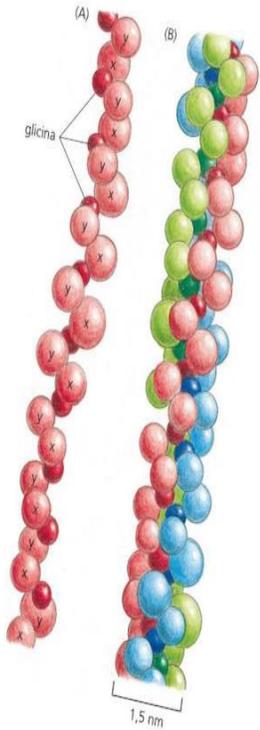
- **PAIN TREATMENT** in **OSTEOARTHRITIS**
- **REDUCED MOBILITY** in the degenerative or traumatic alterations of
KNEE, HIP and SHOULDER
- **INCREASE THE VISCOELASTICITY** of the **SYNOVIAL FLUID**

WHY THE NAME



IT'S the ONLY PRODUCT containing silkworm collagen!

COLLAGEN



The collagen basic structure is a **TRIPLE HELIX** made by different combinations of **type a1 and type a2 polypeptide chains**.

The main characteristic of the typical collagen molecule is its long helical, rigid, triple filament structure, in which three collagen polypeptide chains (the α chains) are wound each other in a **SUPER HELIX** similar to a rope

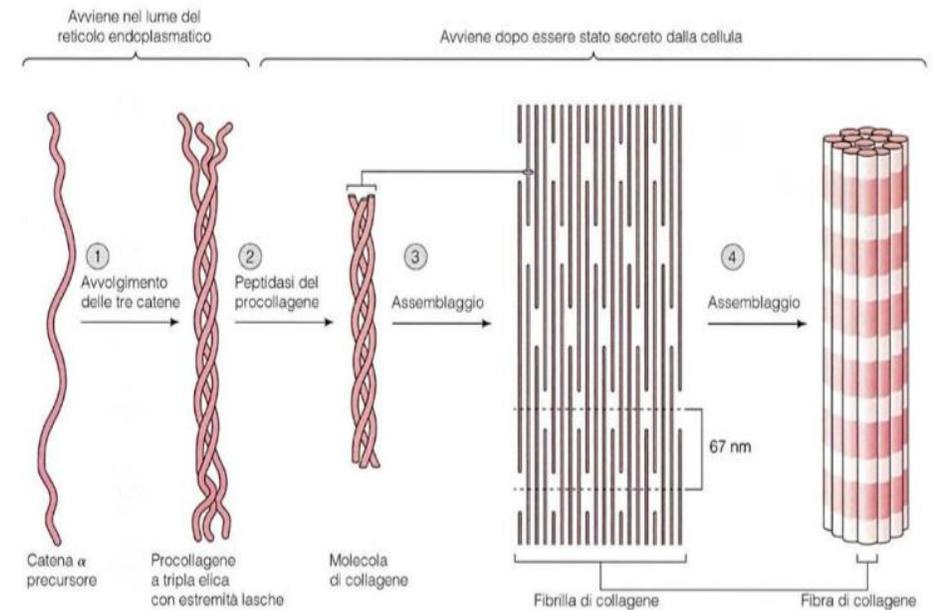
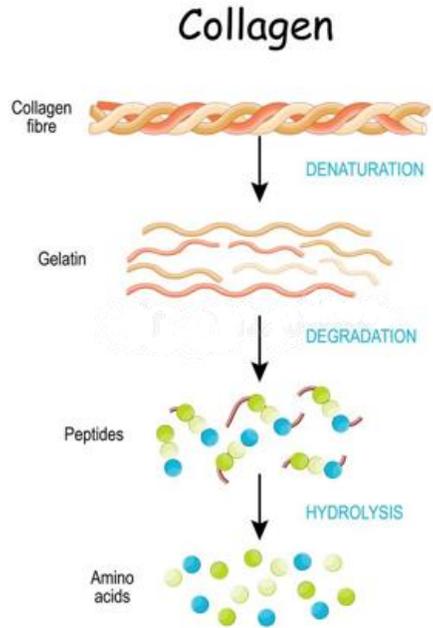


Figura 11-3

Standard COLLAGEN



Type I standard triple helix collagens, like the BOVINE, OVINE, PORCINE must be inserted in high quantities in their different compositions because the digestive process drastically reduces their bioavailability.

VS

NEOSILK

This **COLLAGEN** is **NOT** the standard triple helix collagen, but is directly the

α 1 hydroxylated type I COLLAGEN

Fundamental element of the endogen collagen production process.
DIRECTLY STIMULATES THE COLLAGEN FIBRIL CREATION PROCESS, without any degradation, but maintaining a **high BIOAVAILABILITY**, easing and accelerating the regenerative process.

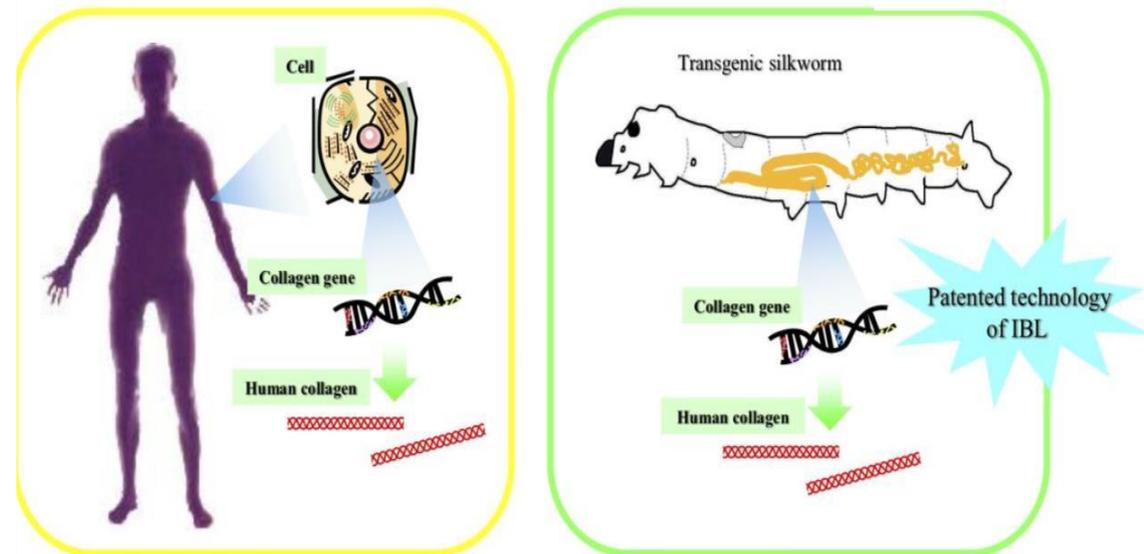
NEOSILK



Silkworm cocoons whence collagen is extracted

The RECOMBINING COLLAGEN, or R α 1 polypeptide chain of the collagen has been obtained by a group of Hiroshima University biologists, which inserted a gene which produces collagen in the silkworm genetic heritage, exactly replacing the one which produces *fibrosin*, one of the proteins which compose silk fibres, produced in the silkworm silk glands.

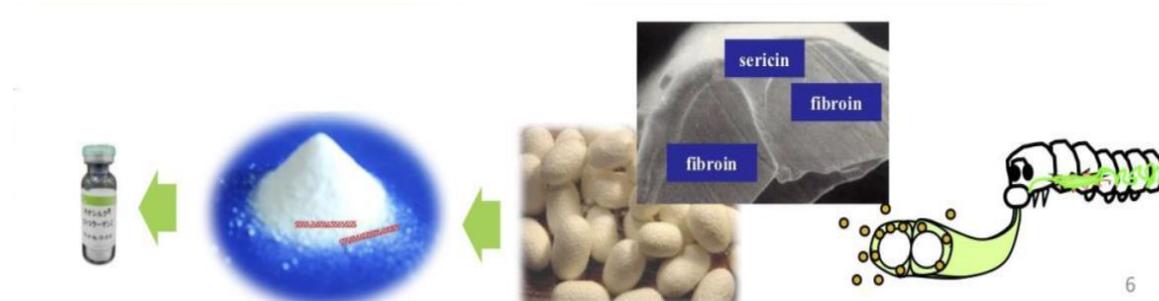
PATENTED TECHNOLOGY



NEOSILK



Will be sufficient to heat the cocoon, killing the larva inside, to extract the silk and separate the strands. Through chemical processes is than extracted the **COLLAGEN**, commercially named **NEOSILK**



NEOIAL HC

α 1 R polypeptide chain of type I COLLAGEN

- **99,9% SIMILARITY TO THE HUMAN TYPE COLLAGEN**
- **GREATER USAGE SAFETY, since ANALLERGIC and NOT IMMUNOGENIC**
- **HIGHLY AND QUICKLY BIOAVAILABLE since α 1 chain**
- **STIMULATES CARTILAGINOUS CELLS PROLIFERATION**

Can be defined PROCOLLAGEN

RECOMBINANT PROCOLLAGEN

It is made by the same aminoacidic chain which can be found in the collagen synthesized in the human organism, the **$\alpha 1$ chain**, while **does not carry the $\alpha 2$ chain**, which can **bring allergens**.

Neosilk, therefore, does not show any allergic reaction risk, as supported by the biologic assessment performed on the substance.

NEOIAL HC

COMPOSITION

Water for injections q.s. to 100, **hyaluronic acid LW 1,8000%**, **hyaluronic acid MW 0,2000%**, **recombinant collagen 0,0005%**, **sodic carboxymethylcellulose 1,8000%**, sodium chloride 0,8000 %, dibasic sodium phosphate dodecahydrate 0,1500%, monobasic sodium phosphate dihydrate 0,0300 %.

Such a low concentration of
RECOMBINANT COLLAGEN is
SUFFICIENT and **EFFECTIVE**

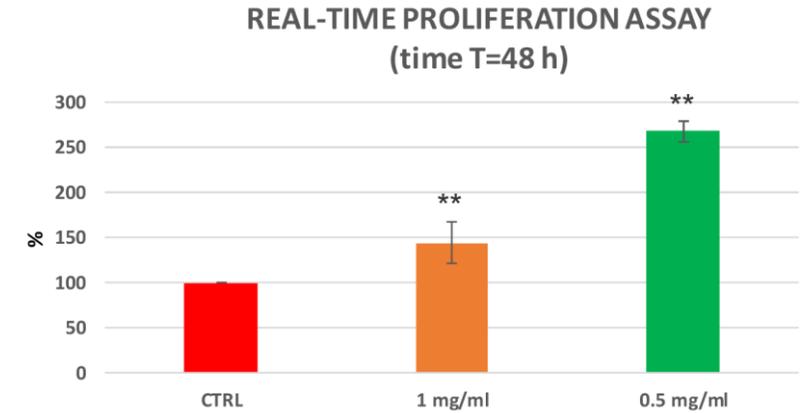
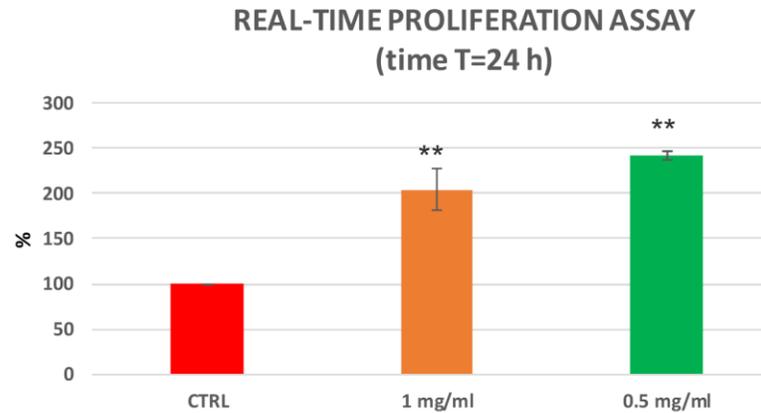
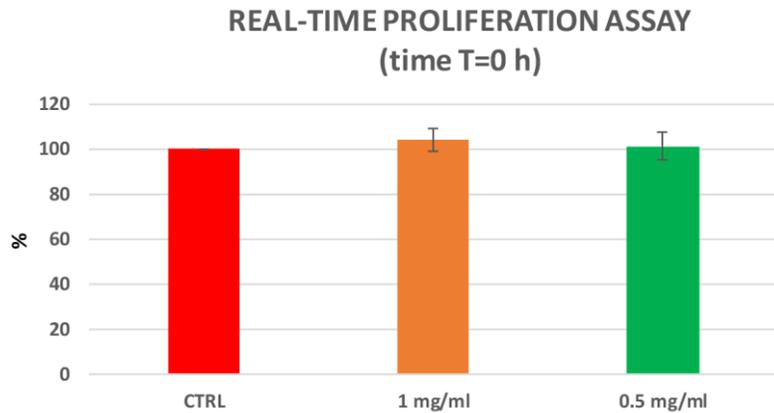
As demonstrated by “**IN VITRO**”
studies on human knee cartilage
chondrocytes



**THE CELLULAR
PROLIFERATION
INCREASE** is achieved
with **LOW DOSAGES**



NEOIAL HC



GROWTH OF CELLULARE PROLIFERATION already after 48 hrs.

In vitro studies demonstrated also the ABSENCE of CYTOTOXICITY, HYPERSENSIBILITY, SKIN REACTIVITY and implantability consequences like CYSTS, GRANULOMAS or ADHESIONS

NEOIAL HC

COMPOSITION

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HYALURONIC ACID

plays the role of viscosupplement, by increasing the viscoelasticity of synovial fluid, offering a mechanical protection on the articular cartilage, preventing bones from entering into contact during the movement.

HA at MW at LW allows a Hyaluronic Acid high concentration, and increased viscosupplementing, warranting, in the meantime, an hydrogel easier extrusion from the syringe

NEOIAL HC

COMPOSIZIONE

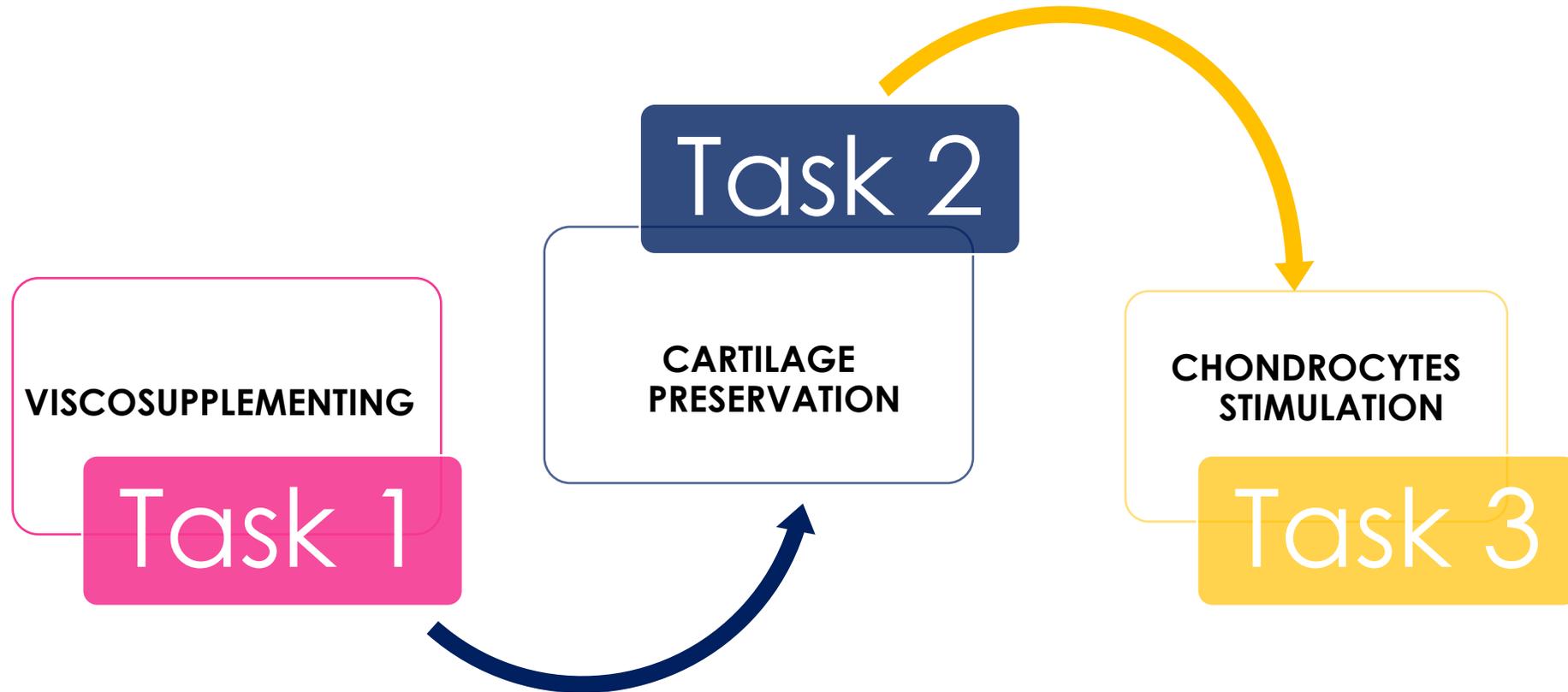
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CARBOXYMETHILCELLULOSE (CMC)

Is a RETICULATED polymer derived from cellulose, used as excipient and food thickener, **fully re-absorbable, biocompatible, which IMPROVES the RHEOLOGIC PROPERTIES and the product VISCOSITY**

Seems also to maintain the endogen hyaluronic acid and to promote the cartilage regeneration thanks to the hyaluronidase enzyme **INHIBITION.**

MAIN TASKS OF *NEOIAL* HC



MAIN TARGET OF *NEOIAL* HC

YOUNG
PATIENT

SPORTY
PATIENT

PATIENT WHOM
SURGERY IS NOT
RECOMMENDED

GONARTHROSIS

COXARTHROSIS

SHOULDER ARTHROSIS

NEOIAL HC

CURRENTLY UNDER CLINICAL STUDY

pre-market, monocentric clinical study

*“Clinical effectiveness and safety of NEOIAL HC (hyaluronic acid + Collagen)
for intra-articular use in the severe knee osteoarthritis.”*



Azienda sanitaria locale
Lanciano Vasto Chieti



Ministero della Salute

STUDY PROTOCOL

CLINICAL STUDY

Goal :

Evaluation of the NEOIAL HC safety and effectiveness parameters in the infiltrative treatment for severe knee osteoarthritis. The patients suffering from severe knee osteoarthritis will be treated with **3 40mg. Infiltrations of NEOIAL HG, at a distance of one week, followed by a fourth infiltration of the same product one month after the third one.**

15 patients will undergo the infiltrative treatment. The patients will be followed with a baseline clinical evaluation, reporting of adverse events after each infiltration and, later, at the end of the treatment, 3 and 6 months of follow-up.

NEOIAL HC

METHODS OF USE



40 mg (2 ml) – **3** infiltrations at a distance of 1 week each other, followed by a possible infiltration after 1 month, at the discretion of the doctor



60 mg (4 ml) – **2** infiltrations at a distance of 1 week each other, followed by a possible infiltration after 1-2 months, at the discretion of the doctor



80 mg (4 ml) – **1** single infiltration followed by a possible further infiltration after 1-2 months at the discretion of the doctor.

NEOIAL HC

PRECAUTIONS – WARNINGS – USEFUL INFORMATION

- The product should not be injected in the presence of **an infected or severely inflamed joint**.and in case of infections in place or **inflammatory conditions of the skin** in proximity of the infiltration site.
- Before the injection **suck any possible joint effusions** and prepare the site with an **appropriate disinfectant**. The use of quaternary ammonium compounds disinfectants is not recommended because, in presence of hyaluronic acid, can promote the **precipitates formation**.
- Inject NEOIAL HC slowly into the joint, possibly at **room temperature**.
- Do not undergo the joint to **excessive weights** the hours after the injection.
- As there is no evidence from clinical trials in **pregnancy** or breastfeeding, the use is not recommended
- Safety and efficacy of NEOIAL HC use with other intra-articular treatments is not ascertained. Therefore, **avoid the administering** of NEOIAL HC **simultaneously to other** intra-articular products to prevent any possible alteration.
- Rarely reactions on the injection site are reported, as **pain, swelling/effusion, heat, redness, itch and synovitis**. Symptoms are bearable and temporary; spontaneously disappear in few days keeping the limb at rest with the application of ice. As for every intra-articular treatment, it may occur septic arthritis in rare cases if infection is not administered in compliance with general precautions of asepsis.

NEOIAL HC

1. IS THE **FIRST** TREATMENT FOR INTRA -ARTICULAR USE WHICH COMBINES DOUBLE MOLECULAR WEIGHT **HYALURONIC ACID** WITH **SILKWORM COLLAGEN**
2. SILKWORM COLLAGEN HAS A **99,9% SIMILARITY** WITH HUMAN COLLAGEN, THEREFORE ALLERGY RISKS ARE PRACTICALLY ABSENT
3. DOES NOT LIMIT TO BRING A **VISCOSUPPLEMENTING ACTION**, BUT INDUCES AND STIMULATES THE **CARTILAGE FORMATION** THANKS TO THE DIRECT ACTION OF THE COLLAGEN ON THE **CHONDROCYTES**.