

**COMPOSITION**

Equine type I collagen powder.

**DESCRIPTION**

Each pack of NITHYA contains 3 glass vials containing 70 mg of sterile, non-pyrogenic equine type I collagen powder.

**INDICATIONS**

Time- and light-induced ageing of the face, neck and hands. The use may be extended to the body at the doctor's discretion. Indicated for the regeneration of the connective tissues of the dermis and hypodermis, through a fibroblast-stimulation and neocollagenesis mechanism.

For the correction of genetic malformations, such as, for example, skin hypotrophy and hypotonia and poor skin elasticity.

**CONTRAINDICATIONS**

- Do not inject NITHYA into the eye contour region (eyelids, crows' feet) or glabellar area.
- NITHYA may only be used on circles under the eyes by doctors who have received special training on this technique and have a good knowledge of the physiology of this area.
- Do not inject into the blood vessels (intravascular use).
- Do not apply excessively for corrective action.

**DO NOT USE:**

- on patients suffering from epilepsy that is not controlled by medical treatment;
- on patients prone to developing hypertrophic scars;
- on patients with known hypersensitivity to collagen;
- on patients with porphyria;
- during pregnancy and breastfeeding;
- on children;
- on areas of inflamed and/or infected skin (acne, cold sores, etc.);
- in immediate combination with laser treatment, deep chemical peeling or a dermoabrasion procedure. Do not inject after a superficial peeling procedure in the presence of significant inflammation.

**DIRECTIONS**

Dilute the collagen powder in the 70 mg vial to obtain a 5 mL suspension in sterile saline solution or double-distilled water.

NITHYA should be made into a suspension immediately before use and it is disposable. Administer using small-gauge needles (30 G), into the deep part of the dermis or the dermal/hypodermal junction, using the picotage technique. Distribute the product over the area to be treated and massage gently.

**DOSAGE**

Three applications, 2 weeks apart; the application cycle may be repeated after three months from the last application.

## **PRECAUTIONS FOR USE/ SPECIAL WARNINGS**

Use the normal precautions for use after intradermal infiltrations.

As for any other percutaneous treatment, use of the product may involve the risk of an infection.

Treatment may cause a slight prickling feeling, which will disappear in a few minutes. The treated area may present reactions commonly associated with injections, such as swelling and rash, which disappear spontaneously within a few hours of treatment.

Do not use in the case of known individual hypersensitivity to the product.

Treatment is not indicated in patients with vascular collagenopathies and autoimmune diseases of the connective tissue (connective tissue diseases).

Do not inject into infected or inflamed skin. Although there are no specific known contraindications, the product should not be used during pregnancy and breastfeeding

The doctor's technical skill is of paramount importance to the success of the treatment; therefore, the device must be used by doctors who have received specific training on the technique to be used when injecting fillers.

Any change to or use of this product other than the conditions of use described in this document may be detrimental to its sterility and performance, which may no longer be guaranteed.

Before starting treatment, patients must be informed of the indications and contraindications of the device, its incompatibilities and any side effects that could occur. Before injecting, carefully disinfect the area to be treated.

Inject slowly. Failure to apply these precautions may result in the needle coming out and/or product leakage from the Luer lock.

The amount of product to be injected depends on the type of area to be corrected.

After the injection, it is important to massage the treated area in order to guarantee uniform product distribution.

## **INTERACTIONS**

There are no known interactions with other substances.

## **SIDE EFFECTS**

Unknown.

The product is hypoallergenic. No side effects have been reported.

The patient must be informed of the existence of potential secondary effects associated with this device, which could occur either immediately or after a certain period of time. These may include, but are not limited to:

- inflammatory reactions (redness, oedema, rash, etc.), sometime associated with itchiness and/or tenderness when touched, which may occur after the injection. These reactions may persist for a week;
- haematomas;
- hardening or nodules at the injection sites;
- colouring or discolouring of the injection area;
- poor or incomplete efficacy of the filler treatment;
- cases of necrosis of the glabellar, abscesses, granulomas and immediate or delayed hypersensitivity have been described in literature after collagen injections. These potential risks must therefore be taken into consideration;
- if inflammatory reactions persist for more than a week or if other side effects occur, the patient must promptly contact his/her doctor, who will prescribe suitable treatment in order to solve the reactions;
- any other side effects associated with the injection of the product must be reported to the distributor and/or manufacturer.

**WARNINGS**

Make sure the packaging and glass vials are intact before using. The device is for disposable only; do not reuse any residues after first opening. Quality and sterility may only be guaranteed for vials/ packs that are sealed at the outset. Dispose of responsibly. Check the expiry date and do not use after the expiry date indicated.

**KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.**

**TRANSPORT AND STORAGE**

NITHYA must be transported and at a temperature no higher than 25°C, in a dry place and in its original packaging.

Protect against direct sunlight; handle with care.

Store at between 0 °C and 30 °C.

**PACK SIZE**

Each pack contains 3 glass vials containing 70 mg of collagen powder and the instructions for use.

**MANUFACTURER**

EURORESEARCH S.r.l. - Via Larga, 2 -20122, Milan - Italy - Tel. +39 02 8055660