



Injectable for intra dermal implant

Performa

**ONLY TO BE ADMINISTERED BY APPROPRIATELY
TRAINED HEALTHCARE PROFESSIONALS**

**WHO ARE QUALIFIED OR ACCREDITED IN
ACCORDANCE WITH NATIONAL LAW.**

**Do not use the product for applications
other than those indicated in this leaflet**

DESCRIPTION

Sunekos® Performa is an implantable medical device.

It is an injectable and resorbable solution, sterilized by filtration, based on non-cross-linked (linear) hyaluronic acid and a specific cluster of six amino acids.

Hyaluronic acid is a critical component of the extracellular matrix of most tissues, including the skin.

Tissues compromised by trauma or ageing processes show a lower level of hyaluronic acid, which results in a loss of hydration.

Thanks to its hydrophilic nature, hyaluronic acid draws and retains water in the extracellular space, resulting in an increase in the volume of the dermis and greater compactness.

Amino acids are able to reduce the degradation process of hyaluronic acid by the enzyme hyaluronidase, promoting a longer permanence of HA "in situ" and therefore greater effectiveness.

In addition, they have a moisturizing, buffering and pH balancing function.

Sunekos® Performa is packaged in single-use/single-patient doses.

INTENDED USE

Sunekos® Performa is intended to:

- integrate the extracellular matrix by exerting a filling effect on anatomically depressed areas of the skin, such as wrinkles and folds, promoting the normalization of imperfections.
- promote the restoration of hydration and the physiological elasticity of the skin tissue.

DESCRIPTION

Sunekos® Performa is indicated for the correction of mild to moderate imperfections and depressions of the skin of the face and neck.

Treatment with Sunekos® Performa is intended for adults with no gender differences and aged 18 years and over.

PACKAGING

The package contains:

- 2 x 3.5 ml vials of a sterile non-cross-linked (linear) sodium hyaluronate gel and a specific cluster of 6 amino acids;
- 2 Patient Implant Card (PIC);
- 2 Traceability Labels;
- 2 Patient Leaflets;

The package does not contain needles or syringes.

COMPOSITION

Each vial contains: Sodium Hyaluronate (50 – 250 kDa) 35 mg, Glycine 38.6 mg, L-Alanine 29.2 mg, L-Proline 29.1 mg, L-Valine 21.5 mg, L-Leucine 5.4 mg, L-Lysine HCl 4.2 mg, Water for injections.

PRECAUTIONS FOR USE

Only to be administered by healthcare professionals with appropriate training and experience and in-depth knowledge of the anatomy of the injection site and adjacent areas, especially the periocular area, and who have been trained in the technique.

Before treatment, the healthcare professional should take a thorough medical history to ensure that there are no contraindications for use and should inform the patient of the methods of administration, warnings, precautions, possible side effects, and additional interventions necessary to maintain the results.

It is also recommended that the healthcare professional use extreme caution on patients treated with permanent or temporary implants in the treatment area as no clinical data are available on the possible interactions.

HOW TO USE

The device can be injected into the following areas:

- face: frontal, periocular, perioral, zygomatic/malar area, cheeks, nasolabial area, mandibular border and chin region;
- neck.

Inject the product into healthy skin using sterile syringes.

The use of a needle between 27 – 30 G is suggested, although the choice is the responsibility of the healthcare professional who performs the injection in relation to the technique used.

Before starting the procedure, disinfect the area to be treated and, if necessary, the healthcare professional can adopt an anaesthetic treatment.

After needle insertion, inject the product slowly with the minimum amount of pressure needed.

It is suggested to carry out an initial cycle of 3 sessions with an interval of two weeks from each other by injecting the medium-deep dermis of the face in the areas indicated above. However, it is suggested that the healthcare professional assess the specific condition of the skin and the patient's needs.

The amount of product required for the treatment changes with the width and depth of the area to be treated.

The maximum injectable dose for a full-face treatment is 3.5 ml.

After the product has been injected, proceed, if necessary, to a gentle massage of the treated area.

The protocol can be repeated, if needed, every 6 months.

It is essential that the healthcare professional records the details of the treatment and the patient, in this regard the operator can apply the additional label supplied with the package to the patient's file.

After the procedure, the healthcare professional must give the Patient Implant Card (PIC) duly filled in to each patient (please refer to the legend of the symbols for instructions on how to fill it in).

CONTRAINDICATIONS

Contraindicated in case of hypersensitivity or ascertained allergy to the components.

It should not be used in persons under 18 years of age.

Do not use in pregnant or lactating women.

Do not inject if there is inflammation and/or active infection.

Do not use in patients on ongoing anticoagulant therapy.

Do not use in patients with systemic soft tissue autoimmune diseases, ongoing neoplastic diseases and/or undergoing immunosuppressive and chemotherapy treatments.

The product should not be used at the same time as other aesthetic medicine or plastic surgery procedures.

WARNINGS

There are no known interactions with drugs and medicinal substances.

Do not use if the package is open or damaged.

Do not use after the expiration date. The expiration refers to the product that is closed and properly stored.

Do not resterilize.

Do not freeze.

Do not mix with other injectable products.

Do not use at the same time as other injectable products, except for Sunekos® 1200, which belongs to the same product line.

Use in an aseptic environment observing appropriate techniques.

Use as soon as the package is opened, the product is single-use/single-patient and should only be used in a single session, reuse of the product for separate applications is explicitly prohibited and may cause infection for the patient. Do not expose the treated area to heat sources until the swelling has been reabsorbed.

The product is for intradermal injection, do not use for applications other than those indicated.

Do not inject intramuscularly or intravascularly, introduction of the product into the vascular system may lead to embolism, vessel occlusion, ischaemia or infarction.

Rare but serious adverse events associated with the intravascular injection of soft tissue fillers containing hyaluronic acid into the face are known in the literature, including temporary or permanent visual disturbances, blindness, cerebral ischemia or cerebral haemorrhage, resulting in stroke, skin necrosis and damage to underlying facial structures.

Stop the injection immediately if the patient has any of the following symptoms, including changes in vision, signs of stroke, pale skin, or unusual pain during or immediately after the procedure.

If an intravascular injection occurs, the patient should receive immediate medical attention and possibly an evaluation by an appropriate specialist physician.

Please note that the aforementioned adverse events have not been reported in relation to the administration of Sunekos® Performa.

After the injection, to prevent any form of contagion, carefully close the needle with its cap and dispose of it as hospital waste.

SIDE EFFECTS

The product is characterized by high tolerability. However, local reactions may rarely occur, due to phenomena of subjective sensitivity to one or more components or malpractice, which may manifest with pain, sensations of heat and/or itching, edema, inflammatory reactions, bleeding and hematomas. The reactions usually resolve within a few days.

No overdose phenomena are known.

In case of undesirable adverse events not described above or if the aforementioned side effects persist beyond the indicated duration, please contact your doctor and/or the healthcare professional who carried out the treatment.

PATIENT WARNINGS

Before the injection, the healthcare professional must provide the patient with the informed consent and the patient leaflet, which contains all the information useful to the patient, such as indications, contraindications, and known side effects. After the treatment, the healthcare professional must fill in and give the patient the Patient Implant Card (PIC) included in the package (please refer to the symbol legend for instructions on how to fill it in).

DOSAGE AND ADMINISTRATION

The maximum injectable dose for a full-face treatment is 3.5 ml.

The injection should be carried out following the technical and aseptic standards prescribed for this method of administration.

Repeat the treatment as described in the "How to use" section.

DISPOSAL METHOD

Do not disperse in the environment.

The product must be disposed of as hospital waste.

STORAGE METHOD

Sunekos® Performa should be stored at a temperature between 5°C and 25°C.

Do not store in the fridge. Do not freeze. Store in a cool, dry place, away from moisture and heat sources.

Report any adverse event and/or serious incident that may occur in relation to the device to the manufacturer, the distributor and the competent authority of the Member State where the user and/or patient is established.

The Manufacturer declines all liability for direct, indirect or consequential damage caused by incorrect or abnormal use of the Sunekos® Performa medical device.

This leaflet is in compliance with TGA Medical Device Essential Principles.

The summary of safety and clinical performance is available at the following link: [\[TBD\]](#)

BASIC UDI-DI: **80217560085Y**




















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SYMBOL LEGEND

	CE marking in accordance with EU M 93/42/EEC and notified body number
	Expiration Date
	Sterilized by moist heat
	Do not reuse / Single-use only
	Keep away from light
	Keep away from moisture
	Unique device identification
	Medical device
	Name and address of the healthcare professional or healthcare facility
	Caution
	Name and address of the Manufacturer
	Batch number
	Do not use if the package is damaged
	Do not use if the package is damaged
	Temperature limits
	Do not disperse in the environment
	Consult the instructions for use
	Patient identification
	Date of treatment