280

79

52

1200

sunekos

ICF SUMI VE 230130 REV.04

COMPOSIZIONE - *COMPOSITION - COMPOSITION*
Acqua p.p.i, Sodio ialuronato ad alto peso molecolare, Glicina, L-Prolina, L-Leucina, L-Lisina HCl, L-Valina, L-Alanina.

Water for injection, high molecular weight Sodium Hyaluronate, Glycine, L-Proline, L-Leucine, L-Lysine HCl, L-Valine, L-Alanine.

Eau PPI, Hyaluronate de sodium à masse moléculaire élevée, Glycine, L-Proline, L-Leucine, L-Lisine HCl, L-Valine, L-Alanine.

Fabbricante/*Manufacturer/Fabricant*
PROFESSIONAL DIETETICS S.p.A.
Via Ciro Menotti, 1/A - 20129
Milan - Italy

STERILE

CE 0373

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CONTENUTO - *CONTENT - CONTENU*
2 x 1,5 ml flaconi - *bottles - flacons*

Prodotto destinato all'uso di personale sanitario
Health care professional use only
Ce produit est destiné à une utilization par le personnel médical

MADE IN ITALY

sunekos 1200

HY6AA

PLAAT FORM

Iniettabile per impianto intradermico
Injectable for intradermal implant
Injectable pour implant intradermique

professional dietetics

DE Zum injizieren in die dermis
ES Inyectable para implante intradérmico
RO Injectabil intradermic
RU Средство для инъекций внутрикожных имплантатов
UA Ін'єкція для внутрішньошкірної імплантації
PL Wyrób do wstrzykiwań śródskórnych
TR Deri alti implantina enjeksiyon için
PT Injetável para aplicação intradérmica
AR حقنة للزرع داخل الجلد
FA ماده تزریقی زیر جلدی
DA Injicerbar til intradermal implantering
FI Ihonsisäisesti injisoitava implantti
IS Innsprautun fyrir fyllingu í húð
NO Injiserbar for intradermalt implantat
SV Injektionsbehandling för intrakutant implantat
BG Инжекционен интрадермален имплант

LOT

82

220

LATO STAMPA TESO

SUNEKOS 1200

SG20-016

18.02.2020

Sunekos Injectable 1200	
Plastificazione	Opaca senza riserve
Stampa	6 colori: CMYK (NERO IN SOVRASTAMPA) + PANTONE 302 (blu) + PANTONE Cool Gray 10

SUNEKOS 1200

Fabbricante / Manufacturer / Fabricant
PROFESSIONAL DIETETICS S.p.A.
Tel. +3902744020

1200

professional® dietetics

sunekos

1200

Injectable for intradermal implant

EN

THIS PRODUCT IS TO BE USED EXCLUSIVELY BY HEALTH CARE PROFESSIONAL

Do not use this product for any applications that are not the ones listed in this information leaflet

INDICATIONS

Sunekos 1200 is an implantable medical device, manufactured in compliance with Directive 93/42/EEC MD, to be used for the treatment of skin imperfections such as: Nasolabial folds; Perioral lines; Face scars and acne scars; Glabellar lines; Forehead lines; Areas of the face that need additional facial tissue (cheeks, chin, cheekbones, lips); Neck, chest, body.
Sunekos 1200 modifies the structure of mature skin, restoring volume, filling wrinkles and folds in the skin and in scar sites. It is suitable for creating a temporary increase in the volume of skin tissue.

DESCRIPTION

Sunekos 1200 is a medical device that is sterile, injectable, non-pyrogenic, biocompatible, re-absorbable, made with hyaluronic acid and amino acids. Hyaluronic acid is one of the main elements in the connective tissue underlying the dermis. After injection into the dermis, Sunekos 1200 spreads evenly in the skin tissues as a result of its viscoelastic properties, providing hydration, elasticity and support to the dermis.

COMPOSITION
Water for injection, high molecular weight Sodium Hyaluronate, Glycine, L-Proline, L-Leucine, L-Lysine HCl, L-Valine, L-Alanine

PACKAGE
The box contains:
• One 1.5 ml bottle (HA) containing high molecular weight Sodium Hyaluronate sterile gel
• One 1.5 ml bottle (AA) containing a sterile solution of amino acids

MECHANISM OF ACTION
Sunekos 1200 must be injected into the skin as integration to the intercellular matrix and to increase intracutaneous volume, thus restoring skin hydration and the natural elasticity of the skin.

DOSAGE AND ADMINISTRATION
Sunekos 1200 must be administered by a physician.
Before administering Sunekos 1200 the physician must gather an accurate medical history and check the patient's conditions, in order to ensure that there are no contraindications of any kind to the implantation procedure. The physician must also inform the patient about what the operation consists in, its nature, the precautions and possible individual results, the duration of the operation, the result that can be achieved and how to maintain it.
Cleanse the area of the implant with antiseptic solution.
An anaesthetic cream can be applied about 30 minutes before the operation (or according to the specific instructions of the chosen product).
Use a sterile syringe to collect the amino acid solution in the AA bottle and to transfer it into the HA bottle containing the hyaluronic acid. Shake the HA bottle well so that the solution is clear. Change the syringe's needle before implanting.
Collect the reconstituted liquid with a sterile needle and inject into the

mid-deep dermis. The procedure is always at the physician's discretion.
The physician will choose the needle depending on the implantation technique used.
Repeat the operation weekly for four-six consecutive weeks (or with a difference frequency, established by the doctor carrying out the operation).

CONTRAINDICATIONS

Do not use in the case of known hypersensitivity to the ingredients.
Do not implant if there is skin irritation and/or ongoing inflammation processes in the area where the device is to be implanted.
Do not use on patients with coagulation factor disorders or in the case of ongoing anticoagulation therapy.
There are no known overdose events.
There are no known side effects.
There are no known interactions with drugs and medicinal substances.
Very occasionally there may be local reactions resulting from hypersensitisation phenomena, with symptoms that include oedema, feeling of burning and/or itchiness. The reactions resolve very quickly (no more than two days). Extremely occasionally there may be infections, which are caused by the type of treatment, the technique and environmental conditions.
Although there are no known secondary effects during pregnancy and breastfeeding, in these cases the product should be used only if allowed by a doctor after a careful examination of the patient's medical history.

WARNINGS

The product is for intradermal injection. Do not use for different applications. Not for intravenous injection.
Sterile product. Do not use after the expiry date.

Do not sterilise again.
Do not mix with other implants and/or injectable substances.
It is packaged in single-use/single patient doses. Use only in one session. Using the reconstituted product for separate applications is forbidden, because it may cause infection in the patient.
Apply the adhesive label in the box onto the patient's medical file (to be filed by the physician).
Keep out of the reach of children.

DISPOSAL

Do not release into the environment.
The product must be disposed of as medical waste.

STORAGE

Sunekos 1200 must be stored at a temperature between 5°C and 25°C.
Do not store in a refrigerator. Do not freeze. Store in a cool, dry place, away from moisture and sources of heat.

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sunekos 1200

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