- **SKIN-F 22**

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medical Device

2. Qualitative composition

1 ml syringe contains:

Components
Water p.p.i.
Hyaluronic acid 22mg/ml
BDDE
Glycine
L-proline

3. Pharmaceutical form

Injectable syringes

4. Clinical information

4.1 Indications

The product being medium cohesive is particularly indicated for the correction of lips and fine wrinkles.

4.2 Method of administration and duration of treatment

- ✓ Before injection of the product, thoroughly disinfect the area to be treated with iodopovidone or chlorhexidine-containing disinfectant..
- ✓ Unscrew the protective cap of the syringe.
- ✓ Screw the needle firmly onto the luer-lock attachment of the syringe.
- ✓ Gently press the plunger to remove any air from the product.
- ✓ If the needle is obstructed, do not increase the pressure on the piston, but replace the needle.
- ✓ Slowly inject the product following the retrograde sliding technique in the superficial layer of the dermis in suitable quantities in the following points: crow's feet, nasogenetic wrinkles, barcode, lip contour, thin lips, marionettes.
- ✓ During injection, the product can be shaped by the doctor with the contralateral hand.
- ✓ At the end, gently massage the treated area to better distribute the product.

A session every 8 months.

4.3 Contraindications

SKIN F 22 is contraindicated in the following cases:

- ✓ In association with chemical peels, laser treatments or dermabrasions. The doctor will determine the necessary waiting time before giving the injection.
- ✓ In the blood vessels.
- ✓ In patients with a tendency to develop hypertrophic scars.
- ✓ In patients with infections and inflammations (acne, herpes, dermatitis, etc.) in situ or near the area subject to treatment.
- ✓ Patients treated with anticoagulants.
- ✓ Patients undergoing radiotherapy or ultrasound therapy in the area to be treated.
- ✓ Patients with hypersensitivity to hyaluronic acid.
- ✓ Patients with untreated epilepsy.
- ✓ Patients with known hypersensitivity or allergy to any of the components.
- ✓ Patients with a skin condition or alteration of any kind.
- ✓ In pregnant or lactating women or children.

4.4 Special warnings and precautions for use

- Don’t use the product after it expires.
- Don’t use the product if the package is damaged, opened or stored improperly.
- The contents of the package are single use and can not be re-sterilized.
- Once the package has been opened, the product must be used immediately: the remaining product must be disposed of.
- Do not inject the product contained in the same syringe with various patients, to avoid any risk of cross-contamination.
- Do not mix the product with other substances.
- Do not add drugs to the product.
- The contents of the syringe are single use and its reuse can result in the loss of sterility with serious consequences for the patient's health.
- The patient should avoid, in the vicinity of the treatment, the intake of substances that act on the fluidity of the blood (aspirin, NSAIDs, Vitamin C and Vitamins E), in order to minimize the possibility of bleeding or bleeding of the injected areas.

- The use of the product must be absolutely excluded in areas where there are mammary, tendon, bone and muscle implants.
- For patients with a history or a declared auto-immune disease, the doctor will need to decide on a case by case basis, depending on the nature of the disease and the associated treatment. It should also ensure accurate monitoring of these patients, in particular will have to propose a preliminary double test and not subject them to injection if the disease is evolutionary.
- Patients with a history of streptococcal disease, such as relapsing angina or acute rheumatism, must undergo a preliminary double test before any injection. In case of acute articular rheumatism, with cardiac localization, it is recommended not to subject the patient to the injection.

4.5 Interactions with medicinal products and other forms of interaction

Not known

4.6 Pregnancy and lactation

Use during pregnancy and lactation is not recommended

4.7 Effects on ability to drive and use machines

Nobody

4.8 Side effects

The doctor should inform the patient about potential undesirable effects resulting from the use of the product, which may occur immediately or after a certain period of time. Some adverse reactions have been reported in the scientific literature after the injection of hyaluronic acid. They include, but are not limited to:

• Inflammatory reactions (redness, edema, erythema, etc.) accompanied by pruritus or pressure pain or both;

• Ecchymosis/ hematomas;

• Induriments or nodules in the injection area;

• Stains and color changes around the injection area;

• Reactions of intolerance;

• Hypersensitivity in the treated area;

• Infection;

• Low filling effect;

• Granuloma;

• Dislocation of the material;

• Numbness;

• Lumps;

• Necrosis;

• Papules and nodules in the injection area;

• Allergic reactions.

Immediately inform your doctor about any adverse event (mentioned above or otherwise) if it lasts longer than 7 days. The plant must be controlled and treated appropriately.

4.9 Overdose
The syringe is for single use and used only by the doctor.

5. Pharmaceutical information

5.1 Incompatibility

Hyaluronic acid is incompatible with quaternary ammonium compounds, such as paste or 50% solution of benzalkonium chloride. Do not put Skin F 22 in contact with these substances or surgical medical instrumentation treated with such disinfectants.

5.2 Period of validity

36 mesi
The expiry date refers to the intact product, correctly preserved.

5.2 Special precautions for storage

• Store the product at a temperature between 2 ° C and 30 ° C.

• Do not expose to sunlight.

• Do not freeze, do not heat.

5.4 Nature, contents of the container

Primary packaging: polycarbonate syringes and needles 27 G.
Secondary packaging: blister in polyethylene terephthalic glycol (PETG) and box of cardboard.

5.5 Special precautions for disposal and handling

The regulations in use for the disposal of medicines apply.

5.6 Packaging for sale
The SKIN F 22 is available in 1 blister pack and in a blister pack.

6. Holder

Italfarmacia srl – Via Tor Sapienza 7 – 00155 Roma

7. Authorization number of the I.S.S.

Certificato n. EPG-0041-17 All. II

Certificato n. QCT-0044-17 All.II

8. Review date of the text
Ottobre 2018

CE
0373