TOSKANI

FOR PROFESSIONAL USE

TKN HA 3

Producto de ácido hialurónico: 9 mg/ml
Hyaluronic acid product: 9 mg/ml

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EN Hyaluronic acid products 9 mg/ml

CE 1023

Only for professional use

Description

The product is an injectable sterile, pyrogen-free gel composed of a hyaluronic acid from a non-animal origin in a sodium chloride saline solution. The gel is latex free, viscoelastic, clear, colorless and biodegradable. Recommended needle is 30G.

Package Content

Each package contains one disposable graduated and pre-filled 1.6 ml syringe with product. Needles are not included.

Composition

Sodium Hyaluronate 9 mg/ml
Sodium chloride solution 0.9%

Indications

The product is intended to hydrate the skin, fill wrinkles in the superficial dermis and improve the skin quality.

Contra-indications

The product is contraindicated for the following:

- For injection into the eyelids. The application of the product in the under-eye area is to be performed only by specialists specifically trained in this technique who have a sound knowledge of this the area's physiology.
- For injection into the epidermis.
- For patients with a known sensitivity to any of the product components.
- For patients suffering from an acute or chronic inflammation or infection in the area to be treated.
- In patients with a tendency to develop inflammatory skin conditions or hypertrophic scarring.
- For patients with unhealthy or poorly vascularized tissue or with systemic disorders affecting wound healing.
- For patients suffering from skin disease or abnormal skin conditions.
- For patients with a history of anaphylactic reactions.
- For patients treated with aspirin or any other medicine which can affect the healing process.
- For use in regions containing foreign bodies (e.g., silicone, other particulate materials).
- For use in area presenting cutaneous inflammatory and/or infectious process (acne, herpes, etc…).
- For use simultaneously with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is not recommended to inject the product if the inflammatory reaction generated is significant.
- For patients with autoimmune diseases.
- For patients suffering from porphyria.
- For patients suffering from untreated epilepsy.
- For use in breastfeeding or pregnant women.
- For use in patients below the age of 18.

Warnings

- Do not overcorrect.
- Do not inject into blood vessels (intravascular).
- Do not use after the expiry date.
- Do not use if the label is damaged.
- Do not use if the package is open or compromised.
- Do not re-sterilize.
- Do not modify the product; modification may affect its sterility and performance.
- Do not use if device damage is suspected.
- Do not use if particles, coloration, turbidity, or separation are visible in the gel.
- Do not inject an amount greater than 20 ml per 60 kg body mass per year.

Precautions for use

- The product is indicated for intra-dermal injection only.
- The product is to be used by medical practitioners who have undertaken specific training in injection techniques for dermal filling. In using the device, clinical judgment must be made regarding its application.
- As a matter of general principle, injection of a medical device is associated with a risk of infection.
- Only syringe/vial content and injection path are sterile.

- The product is to be used under sterile conditions only.
- Use with caution in patients currently on immunosuppressive therapy. The physician shall therefore decide on the indication on a case-by-case basis, according to the nature of the disease and its corresponding treatment, and shall ensure the specific monitoring of these patients. In particular, it is recommended that these patients undergo a preliminary dual test, and to refrain from injecting the product if the disease is active.
- Patients on anti-coagulation medication must be warned of the potential increased risks of heamoatomeas following injections.
- Use with caution when injecting in proximity to permanent filling implants. There is no clinical data (efficiency and tolerance) about injection of the product into an area, which has been treated with a permanent implant.
- Avoid injecting through scar tissue and/or significantly compromised tissue.
- Injection into inflamed or infected tissue may result in tissue damage or loss.
- Hematomas or seromas may require surgical drainage.
- Major hypersensitivity reaction, inflammation and infection may require implant removal.
- Patients with a record of streptococcal disease (such as recurrent sore throats or acute rheumatic fever), should be tested before treatment. If rheumatic fever is accompanied with heart complications, the product should not be used.
- Injection of the product may be accompanied with mild discomfort; administration of anesthetics should be considered.
- As with all transcutaneous procedures, injection of the product carries a risk of infection. The usual precautions associated with injectable material should be followed.

UNDESIRABLE EFFECTS

Patients must be informed about the common adverse effects reported for hyaluronic acid injectable implants, which may occur immediately or may be delayed. These include, but are not limited to:

- Inflammatory reactions (redness, erythema, oedema) which may be associated with pain or itching.
- Hematomas
- Induration, migration or nodules at the injection site.
- Poor effect or weak filling effect and loss of sensitivity at the site of injection.
- Necroses in the glabellar region, abscesses and granuloma. It is advisable to consider these potential risks.
- Treatment site reactions typically resolve within 24-48 hours. Other adverse effects generally resolve within 2-4 weeks.
- Patients should be advised to promptly report attending any evidence of a serious adverse effect or any adverse effect not mentioned in this leaflet to the attending physician.
- Any other undesirable side effects associated with injection of the product must be reported to the local distributor and/or directly to the manufacturer.

METHOD OF USE

Prior to treatment

- Handle in accordance with standard medical practices and local regulations. For a successful treatment, the product must be used by medical practitioners who have undertaken specific training in injection techniques for dermal filling.
- The product is to be used as supplied. Carefully inspect all parts for damage.
- Carefully inspect visually the gel before injection. Subsequent treatments may be required to obtain optimal results. Allow for at least seven days between treatments, to enable effective evaluation of the implantation outcome.
- Before starting the treatment, patients should be informed of the products indications, incompatibilities, contra-indications and potential side effects. A full patient history should be obtained and the region to be treated should be fully appraised.
- Assess the patient's need for managing pain and apply, if necessary, the most appropriate form of anesthetic. In the event of anesthetic administration, apply ice to the area to reduce local swelling and distention.
- Thoroughly wash the treatment area with soap and water and disinfect with an alcohol swab.

Injecting the gel

Linear threading injection technique, serial puncture injections, tunneling technique or a combination of them can be used, depending on the treated area and severity of the deep deficit. Palpate the region with the free hand to confirm insertion of the needle into the skin layer of interest. Inject the gel slowly while applying even pressure on the plunger rod while slowly pulling the needle backward.

⚠ **Stop the procedure immediately if vascular puncture is suspected.**

If significant resistance is encountered during the injection process, move the injection needle deeper to allow for easier deposition of the implant. If resistance persists, try injecting from a different entry point. In the event of continuous resistance, the injection

needle and/or syringe may have to be replaced.

⚠ **Do not apply excessive pressure to the syringe at any time.**
If immediate blanching occurs, stop injecting and massage the area until color returns to normal. If normal skin color does not return, do not resume the injection process.
Superficial injection or delivery of large quantities may result in discoloration and nodule formation.

⚠ **Stop injection before pulling the needle out of the skin to avoid gel leakage out from the injection site.**
Repeat the procedure if further correction is necessary, but only after thoroughly assessing the treated area and patient status.
After completing the injection, it is important to massage the area treated after the injection in order to ensure that the gel has been uniformly distributed.
If overcorrection has occurred, firmly massage the area to obtain optimal results.

Post injection care

Patients should be advised to avoid extreme activity, and exposure to sunlight and tanning lamps or extreme weather conditions for 24 hours.
Patients should be instructed to apply an ice pack or cold compress to the treated area for 24 hours post- treatment.
Patients should be advised to limit talking, smiling and laughing for one week after the procedure.
Patients treated at the mouth area should be advised to rinse their mouth with a saline solution every 3-4 hours, for one week post-treatment.
If needed, oral analgesics can be used.

Storage

- Storage between 2ºC and 25ºC
- Do not freeze

Disposition

Used needles and syringes/vials must be disposed of according to standard medical practices and local regulations.

Dr. Korman Laboratories Ltd.
23 Yosef Levi Str., Kiryat Bialik 2751123, Israel
Tel.:+972-(0) 46893930, Fax: +972-(0) 46893931
E-mail:info@drkorman.com
Web: www.drkorman.com

EC REP
MedNet EC-REP GmbH
Borkstrasse 10,
48163 Muenster,
Germany

Distributed by: TOSKANI S.L.
Barcelona at
C/ Passatge Ciutadans, 4,
Postal code: 08005, Spain

Regulatory Symbols

	Manufacturer
EC REP	Authorized representative in the EU Community
⚠	Caution
	Consult instructions for use
LOT	Lot number
REF	Catalog number
STERILE A	Sterilized using aseptic processing techniques - fluid path
	Use by
	Do not re-sterilize
	Single use
	Temperature limitation
	Keep away from sunlight
	Keep dry
	Does not contain natural rubber latex
	Do not use if package is damaged
CE	CE mark

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Dr. Korman Laboratories Ltd.
23 Yosef Levi Str., Kiryat Bialik 2751123, Israel
Tel.:+972-(0) 46893930, Fax: +972-(0) 46893931
E-mail:info@drkorman.com
Web: www.drkorman.com

EC REP

MedNet EC-REP GmbH
Borkstraße 10,
48163 Münster,
Germany

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TOSKANI S.L.
Pge. Ciutadans, 4
08005 Barcelona (Spain)
www.toskani.com