HYALUXELLE®

3.2% - 16 mg (H-HA) + 16 mg (L-HA)/1 ml Hyaluronic acid sodium salt

3.2% - 32 mg (H-HA) + 32 mg (L-HA)/2 ml Hyaluronic acid sodium salt

Medical device for intradermal use

Sterile - Single-use

DESCRIPTION

Hyaluronic acid (HA) is a polysaccharide naturally present in the human organism, whose main function is to maintain correct tissue hydration thanks to its intrinsic ability to bind a large amount of water. Hyaluronic acid sodium salt is formed by repetitive chains of disaccharide units of N-acetylglucosamine and sodium glucuronate and is an essential component of the extracellular matrix in the majority of tissues.

HYALUXELLE® is composed of a buffered saline solution of high molecular weight (H-HA) and low molecular weight (L-HA) hyaluronic acid.

The high- and low-molecular-weight HA used in the device is obtained by biofermentation and has not undergone chemical modification processes; this results in excellent tolerability of the product.

In addition, the HA chains with different molecular weight present in **HYALUXELLE®**, thanks to a specific and patented treatment of the solution (***NAHYCO® Hybrid Technology)***, interact with each other, giving **HYALUXELLE®** unique rheological properties that allow higher concentrations of HA to be administered at equal viscosity of the solution.

INTENDED USE

HYALUXELLE® is indicated for adult women. **HYALUXELLE®** intervenes in the physiological process of the reduction of skin hydration, alteration of the elastic fibres and collagen of the dermis with loss of turgor and skin tone, for example in cases of excessive dehydration, weight loss and aging, with relative loss of endogenous HA.

The viscoelastic and moisturising properties of **HYALUXELLE®** allow rehydrating the tissues and creating the optimal conditions to prevent the tissue remodelling.

The HA used for **HYALUXELLE®** is produced by biosynthesis from a natural substrate without further chemical transformation; for this reason, **HYALUXELLE®** has excellent biocompatibility.

INDICATIONS

HYALUXELLE® is indicated for adult women in order to treat the vulvar vestibule in case of vaginal atrophy, dryness, burning or itching (not infectious), vaginal introitus pain during intercourse.

IFU - HiLow hyaluronic acid sodium salt for vaginal use – February 2024

INTENDED POPULATION AND USERS

HYALUXELLE® is indicated for adult women and is to be administered by intradermal injection by qualified personnel only.

HYALUXELLE® IS TO BE SOLD ON MEDICAL PRESCRIPTION ONLY.

COMPOSITION

HYALUXELLE® has consisted by the prefilled syringe with 1 or 2 ml of solution, which contains:

SYRINGE VOLUME	**1 ml**	**2 ml**
FUNCTIONAL COMPONENT		
SODIUM HYALURONATE	16 mg (H-HA) + 16 mg (L-HA)	32 mg (H-HA) + 32 mg (L-HA)
OTHER COMPONENTS		
SODIUM CHLORIDE	8.000 mg	16.000 mg
SODIUM PHOSPHATE	0.205 mg	0.410 mg
WATER FOR INJECTION	q.s. 1.0 ml	q.s. 2.0 ml

POSOLOGY

It is advisable to do an initial cycle of two treatment sessions with an interval of 30 days between one and the next and to reassess the patient six months after the first treatment.

AVAILABLE KITS

HYALUXELLE® is available in kits of 1 prefilled syringe with two 29G x ½" (0.33 x 12 mm) needles in the following volumes:

- 1 ml prefilled syringe (16 mg (H-HA) + 16 mg (L-HA) of hyaluronic acid sodium salt in 1 ml sodium chloride buffered saline solution)
- 2 ml prefilled syringe (32 mg (H-HA) + 32 mg (L-HA) of hyaluronic acid sodium salt in 2 ml sodium chloride buffered saline solution)

The content of the syringe is sterile and pyrogen-free.

Prefilled syringe sterilized by moist heat.

Needle: CE 0197; Manufacturer: Terumo Europe N.V. - Interleuvenlaan 40 - 3001 Leuven, Belgium
Needle sterilized by ethylene oxide.

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INSTRUCTIONS FOR USE

- Carefully unscrew the syringe cap, firmly holding the Luer-lock closing neck between your fingers and being particularly careful to avoid contact with the opening (Figure A).

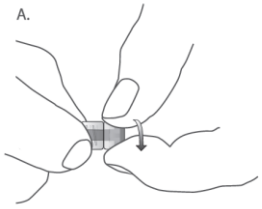

Figure A

- Firmly holding the Luer-lock closing neck between your fingers, screw the 29G needle (included in the kit) tightly onto the closing neck of the syringe until you feel slight pressure so as to ensure an airtight seal and prevent liquid leakage during administration (Figure B).

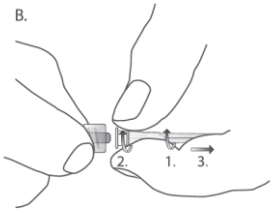

Figure B

- Inject **HYALUXELLE®** at ambient temperature and in strict aseptic conditions.

Suggested injection techniques

Local anaesthesia is suggested and the product should be injected into the deep dermis using a linear retrograde technique at 6 points along the vulvar vestibule (Figure 1 is to be redone and stylized):

1. Anterior commissure: 0.3 ml
2. Anterior right lateral: 0.3 ml
3. Anterior left lateral: 0.3 ml
4. Posterior right lateral: 0.3 ml
5. Posterior left lateral: 0.3 ml
6. Posterior commissure: 0.5 ml

Apply a light massage at the injection sites. This technique allows homogeneous distribution of the product in the vestibule area.

It is advisable to do a second treatment after 30 days and to reassess the patient at the sixth month after the first treatment.

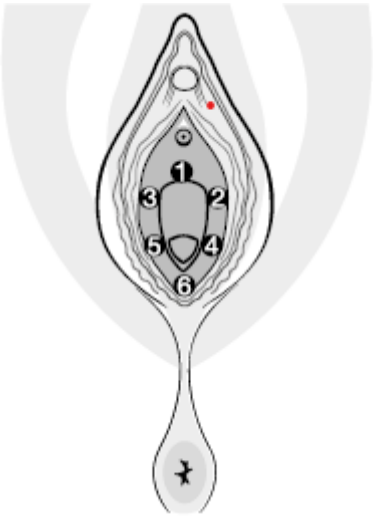

Figure 1

After the treatment:

After the treatment, the implant card must be filled in and provided to the patient; the implant card can be found in the first page of the instruction for use containing in the pack.

Instruction for completing the Implant card

Fill in the fields marked with the following symbols with the information indicated:

	Patient Name or patient ID
	Date of treatment
	Name and address of the implanting healthcare institution Name of medical practitioner**.**

WARNINGS

- The content of the prefilled syringe is sterile. The syringe is packed in a sealed blister pack.
- The outer surface of the syringe is not sterile.
- Do not use **HYALUXELLE**® after the expiry date indicated on the package.
- Do not use **HYALUXELLE**® if the packaging is open or damaged, because the sterility of the product could be compromise.

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- The injection site must be on healthy skin.
- Do not use in pregnant or breast-feeding women.
- Do not inject intravascularly, into the muscles or tendons, or for breast enlargement.
- Do not mix with other products.
- Do not inject into areas where inflammatory processes are present.
- Do not use **HYALUXELLE**® in case of autoimmune diseases.
- Do not use **HYALUXELLE**® in case of collagenopathy.
- Do not use **HYALUXELLE**® in case of inflammation of the connective tissue.
- Do not resterilize. The device is intended for single use only.
- Do not reuse in order to prevent any risk of contamination.
- Store below 25°C and keep away from heat sources. Do not freeze.
- Once opened, **HYALUXELLE** ® must immediately be used and discarded after use.
- **HYALUXELLE**® is indicated for adult patients.
- Keep out of the reach of children.
- Do not use **HYALUXELLE** ® in case of known hypersensitivity or allergies to the components of the product.
- Any air bubble present does not compromise the characteristics of the product.
- Avoid sauna or Turkish bath and sports such as cycling or horse riding and sexual intercourse in the 3 days following the treatment.
- After injection and for the next 3-5 days, advise the patient to avoid exposure to UV rays.

PRECAUTIONS FOR USE

Do not mix **HYALUXELLE**® with disinfectants such as quaternary ammonium salts or chlorhexidine as a precipitate may form.

In order to avoid possible complications, an antiseptic may be used before the injection procedure.

INTERACTIONS

To date, there are no known interactions between **HYALUXELLE**® and other drugs/treatments.

Nonetheless, in case of therapies and/or taking medications in conjunction with the treatment, consult your doctor for more information.

SIDE EFFECTS

Extradermal infiltration of **HYALUXELLE**® may locally cause undesirable effects.

During use of **HYALUXELLE**®, symptoms such as oedema, ecchymosis, erythema, bruising, temporary pain and/or swelling, sensation of heat, reddening or itching may occur at the injection site. These secondary manifestations can be relieved by applying ice on the treated area. They generally disappear after a short period of time.

Physicians must ensure that patients notify them of any undesirable effects that occur after the treatment.
There is no link between the use of HYALUXELLE® and the occurrence of adverse events during pregnancy and breast-feeding, or possible defects in unborn children. However, no specific studies have been conducted on this topic, therefore the use of HYALUXELLE® is not recommended during pregnancy or breast-feeding unless strictly necessary. In this case, please contact your doctor for advice.
In the event of an incident, inform the manufacturer or the competent authority.

OVERDOSE

Follow the posology indicated and if you experience any side effects related to an overdose, contact your doctor or nearest hospital.

CONTRAINDICATIONS

HYALUXELLE® must not be used in conjunction with treatments such as laser (ablative or epilative), peeling and genital whitening treatments.

Do not administer to patients with known hypersensitivity (allergy) to the components of the solution (high and low molecular weight HA, sodium chloride, sodium phosphate and water for injection).

Shelf-life: 36 months.
The expiry date indicates the maximum shelf-life of the medical device referring to the product properly stored in an intact package.

DATE OF LAST REVISION OF PACKAGE LEAFLET

February 2024

DISPOSAL

Do not dispose of the product in the environment after use. Follow local regulations for disposal of the product.

To the following link it's possible to download the Summary of Safety and Clinical Performance:
https://www.ibsa.it/en/chi-siamo/summary-of-safety-and-clinical-performance.html

https://www.ibsa.it/en/chi-siamo/sscp-area-riservata.html

MANUFACTURER

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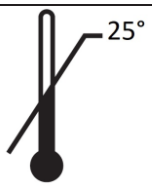
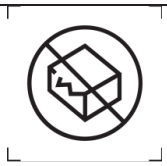
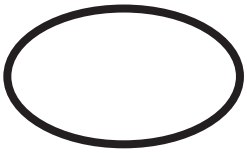
info@ibsaderma.com

CE 0477	 See the instructions for use	 Use by...	 Batch
 Single-use	 Storage temperature	 Sterilized by moist heat	 Do not resterilize
 Do not use if the package is damaged	 The medical device contains a sterile fluid path that has been sterilized by moist heat. Moreover indicates a single *sterile* barrier system with protective packaging outside	 Sterilized by ethylene oxide	**Exp.** Expiry
 Medical Device	 Date of manufacture	 Caution ! Read the warnings carefully	 Unique device identifier
 Manufacturer	 Single sterile barrier system		