Disclaimer:

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MEDICA DEPOT
PROFESSIONAL MEDICAL SUPPLY
X-HA®
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X-HA volume

DESCRIPTION:

X-HA® Volume is a sterile, biodegradable, viscoelastic, clear, colourless, isotonic and homogenized injectable gel. X-HA® Volume consists of cross-linked hyaluronic acid (HA) produced by Streptococcus equi bacteria, formulated to a concentration of 23 mg/ml in a physiologic buffer. Each box contains two syringes, four 27G ½ inch disposable sterile needles reserved for injection of X-HA® Volume, a product leaflet and a set of four labels showing the batch number. One of these labels should be attached to the patient's file and the other should be handed to the patient to ensure traceability.

INDICATIONS:

X-HA® Volume is an injectable biodegradable gel to increase or restore volume of the face, remodel facial contours and correct deeper wrinkles and folds; it is indicated for injection into the deep dermis, subcutis or supraperiosteally.

EXCLUSION CRITERIA:

Do not inject X-HA® Volume around the eye (crow's feet, eye circle or into the eye lids) or glabellar region. X-HA® Volume must not be used in:

- *patients who tend to develop hypertrophic scarring.*
- *patients with a history of autoimmune disease or who are receiving immune therapy.*
- *patients who are known to be hypersensitive to hyaluronic acid.*
- *women who are pregnant or breastfeeding.*
- *patients under 18 years.*

X-HA® Volume must not be used in areas presenting cutaneous, inflammatory and/or infectious processes (e.g. acne, herpes…). Anticoagulated patients or patients receiving platelet aggregation inhibitors (e.g. ASS) should not be treated with X-HA® Volume without consulting their doctors. X-HA® Volume must not be used in association with laser therapy, chemical peeling or dermabrasion.

PRECAUTIONS FOR USE:

X-HA® Volume is only indicated for injections into the deep dermis, subcutis or supraperiosteally. Do not use if packaging has been damaged. Sensitive skin may be pre-treated using a local anaesthetic patch or cream. Please note that anaesthesia may cause redness or local hypersensitivity. There are no available clinical data (efficiency, tolerance) about injection of X-HA® Volume into an area which has already been treated with another filling product. Patients should be advised not to apply any make-up for 12 hours after the injection and to avoid prolonged exposure to sunlight and UV or using saunas or Turkish baths for one week after the injection. If the 27G ½ inch needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle. Do not inject into blood vessels (intravascular). Do not use X-HA® Volume in bones, tendons, ligaments or muscles. Do not inject X-HA® Volume into naevi. Do not overcorrect. Discard the syringe and remaining product after use.

INTERACTION WITH OTHER AGENTS:

There are incompatibilities between sodium hyaluronate and quaternary ammonium compounds such as benzalkonium chloride solutions. Therefore X-HA® Volume should never be placed in contact with these substances or with medical-surgical instruments that have been in contact with these substances.

UNDESIRED SIDE EFFECTS:

Physicians must inform the patient that there are potential side effects associated with implantation of this device, which may occur immediately or may be delayed. These include (non-exhaustive list):

- *Inflammatory reactions (e.g. redness, oedema, erythema,) which may be associated with itching and pain on pressure after the injection. These reactions may last for a week.*
- *Indurations or nodules at the injection site especially in cases of too superficial placement. In a clinical study of similar substances, local mobility of the injected gel was observed; this might be due to the use of too large volume and/or sub-optimal injection technique.*
- *Discoloration of the injection site.*
- *Poor effect or weak filling effect if X-HA® Volume is injected incorrectly. Cases of skin necrosis, abscess formation, bacterial infection, formation of granulomas, cystic and acneiform lesions and hypersensitivity have all been reported in the literature following hyaluronic acid injection. Cases of blindness and transient partial visual loss as the most severe uncommon undesired events due to wrong injection technique have also been reported. It is therefore important to take these possible complications into account. Patients must inform their physician as soon as possible about any inflammatory reactions which persist for more than one week or any other secondary effect which develops. The physician should treat these as appropriate. Any other undesirable side effects associated with injection of X-HA® Volume must be reported to the distributor and/or to the manufacturer.*

METHODS OF USE:

This device is designed to be injected into the deep dermis, subcutis or supraperiosteally by a physician. The technique used is essential for the success of treatment. Therefore this device must be used by doctors who have received specific training in the injection technique to restore volume of the face. To avoid a possible risk of product mobility the patient should be advised not to massage the treatment site for a few days following the injection. Before starting treatment patients should be informed about indications for the device, its exclusion criteria, incompatibilities and potential undesired side effects. The area to be treated should be disinfected thoroughly prior to the injection. Use the 27G ½ inch needle which is provided with the syringe and inject slowly by applying the appropriate injection technique. The amount injected will depend on the deformity which is to be corrected. After the injection, doctors may apply a light massage in order to distribute the product uniformly.

WARNINGS:

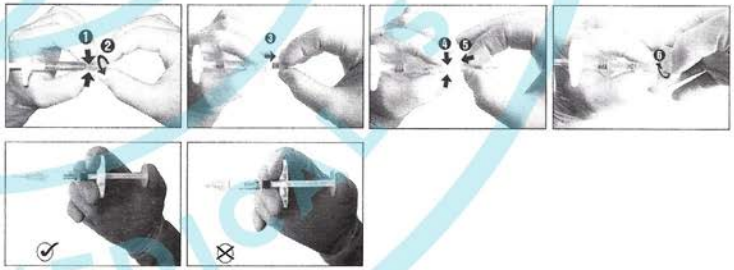
Verify the integrity of the syringe before use. Verify the expiry date on the product label. Do not use any other needle or syringe than provided by the manufacturer. Do not re-use. Do not re-sterilise. The re-use of the product bears risks (e. g. cross-contamination) for the patient. After use the needle must be disposed of in a special container.

INSTRUCTIONS FOR THE CORRECT REMOVAL OF THE TIP CAP:

Hold the Luer Lock Adapter as shown in (1). Twist the cap carefully with the other hand in an anti-clockwise direction (2). Then remove the cap as shown in (3). Do not use a syringe with open or shifted tip cap within the pouch.

INSTRUCTIONS FOR THE CORRECT INSERTION OF THE NEEDLE:

Hold the syringe as shown in (4). Insert the enclosed 27G ½ inch needle firmly as shown in (5). Hold the needle and lock it into position by twisting lightly in a clock-wise direction (6). During application X-HA® Volume should be held as shown in figure 1.



STORAGE:

Store X-HA® Volume at 2– 25 °C (36–77 °F) in a dry place in the original box. Protect from light, heat and frost and handle with care.

COMPOSITION:

Cross-linked sodium hyaluronate 23 mg/ml. Phosphate buffer pH 6.8-7.4 q.s., sodium chloride. One syringe contains 1.0 ml of X-HA® Volume. The syringe is sterilised with moist heat.

Explanation of international symbols:

Prefilled Syringe

STERILE

Needle

STERILE EO

LATEX

Manufacturer:

FILORGA S.A.S.
2-4 rue de Lisbonne
75008 PARIS

CE
0297

Sterimedix:
1 madeley road North Moons Moat Redditch Worcestershire
B98 9NB
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