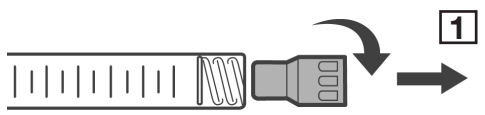

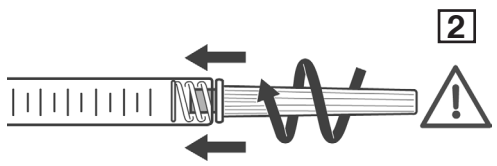

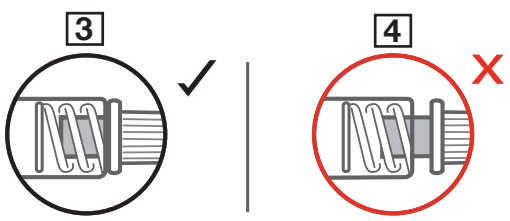

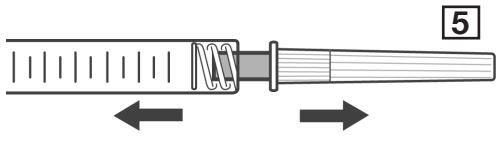

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0459
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HYDRA FILL ® *SoftLine™ MAX*

COMPOSITION

Cross-linked hyaluronic acid	24 mg
Phosphate buffer pH 7.2 q.s.	1 ml

One syringe contains 0.8 ml of ***HYDRA FILL® SoftLine™ MAX***.

DESCRIPTION

HYDRA FILL® SoftLine™ MAX is a sterile pyrogen-free physiological solution of cross-linked hyaluronic acid which is not of animal origin.
The gel is presented in a graduated pre-filled disposable syringe.
Each box contains 2 syringes of ***HYDRA FILL® SoftLine™ MAX***, 4 27G1/2" disposable needles reserved for injection of ***HYDRA FILL® SoftLine™ MAX***, a product leaflet and a set of labels showing the batch number, one of which should be attached to the patient's file and the other should be given to the patient in order to ensure traceability.

STERILISATION

The content of the ***HYDRA FILL® SoftLine™ MAX*** syringes is sterilised by moist heat.
The 27G1/2" needles are sterilised by radiation.

INDICATIONS

HYDRA FILL® SoftLine™ MAX is an injectable implant used for filling mid and/or deep depression of the skin via mid and/or deep dermis injection, as well as for volume increase, definition and pouting of the lips.

CONTRA-INDICATIONS

• Do not inject ***HYDRA FILL® SoftLine™ MAX*** into the eye contours (crow's feet, eyelids) and glabellar region. The application of ***HYDRA FILL® SoftLine™ MAX*** in the bags under the eyes is reserved to specialists specifically trained in this technique and having a sound knowledge of the physiology for this particular area.
• Do not inject into the blood vessels (intravascular).
• Do not overcorrect.
• ***HYDRA FILL® SoftLine™ MAX*** must not be used in :
- patients who tend to develop hypertrophic scarring
- patients who are known to be hypersensitive to hyaluronic acid.
- women who are pregnant or breastfeeding.
- children.
• ***HYDRA FILL® SoftLine™ MAX*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes ...).
• ***HYDRA FILL® SoftLine™ MAX*** must not be used in association with laser therapy, chemical peeling or dermabrasion. For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

• ***HYDRA FILL® SoftLine™ MAX*** is not indicated for injections other than intra-dermal injections and in the mucous membrane of the lips.
• There are no available clinical data (efficiency, tolerance) about injection of ***HYDRA FILL® SoftLine™ MAX*** into an area which has already been treated with another filling product.
• No clinical data is available regarding the efficiency and tolerance of ***HYDRA FILL® SoftLine™ MAX*** injections in patients having a history of or currently suffering from autoimmune disease. Depending on the nature of the disease, the medical practitioner shall therefore decide on the administration and associated treatment on an individual case-by-case basis. He/she shall also ensure the specific monitoring of this type of 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.
• There is no available clinical data concerning the tolerance of the ***HYDRA FILL® SoftLine™ MAX*** injection in patients presenting a history of severe multiple allergies or anaphylactic shock. The medical practitioner shall therefore decide on the indication on a case-by-case basis, according to the nature of the allergy, and shall also ensure the specific monitoring of these at-risk patients. In particular, the decision may be taken to propose a double test or suitable preventive treatment prior to any injection.
• Patients showing a history of streptococcal disease (recurrent sore throat, acute rheumatoid arthritis) shall be subjected to a dual test before any injection is given to them. In the event of acute rheumatoid arthritis with heart complications, it is recommended not to inject the product.
• Patients undergoing anti-coagulant treatment must be warned of the increased risk of haematomas and bleeding during the injection. In the same way, it is recommended to avoid taking aspirin or high doses of vitamin C the week before the injection.
• Patients should be recommended not to apply make-up for 12 hours after the injection and to avoid prolonged exposure to sunlight, UV light, freezing temperatures or using saunas or Turkish baths for the two weeks after the injection.
• If the 27G1/2" needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle.

HYDRA FILL ® *SoftLine™ MAX*

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. ***HYDRA FILL® SoftLine™ MAX*** should never therefore be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.

UNDESIRABLE EFFECTS

Medical practitioners 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 (redness, oedema, erythema, ...) which may be associated with itching, pain on pressure, occurring after the injection. These reactions may last for a week.
• Haematomas.
• Induration or nodules at the injection site.
• Staining or discolouration of the injection site.
• Poor effect or weak filling effect.
• Cases of necroses in the glabellar region, abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid injections have been reported. It is therefore advisable to take these potential risks into account.
• Patients must report inflammatory reactions which persist for more than one week or any other secondary effect which develops, to their medical practitioner as soon as possible. The medical practitioner should treat these as appropriate.
Any other undesirable side effects associated with injection of ***HYDRA FILL® SoftLine™ MAX*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE - POSOLOGY

This device is designed to be injected into the dermis and into the lips by a medical practitioner. The nappage technique can also be used with this product. The technique used for this is essential in the success of treatment and this device must therefore be used by medical practitioners who have received specific training in the injection technique for filling .
• Before starting treatment patients should be informed of the indications for the device, its contra-indications, incompatibilities and potential undesirable effects.
• The area to be treated should be disinfected thoroughly prior to the injection.
• Remove tip cap by pulling it straight off the syringe as shown in fig. 1. Then firmly push the needle provided in the box (fig. 2) into the syringe, screwing it gently clockwise. Twist once more until it is fully locked and has the needle cap in the position shown in fig. 3. If the needle cap is positioned as shown in fig. 4, it is incorrectly attached.
Next, remove the protective cap by holding the body of the syringe in one hand, the protective cap in the other, as shown in fig. 5, and pulling the two hands in opposite directions.
Inject slowly.
Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level.
• The amount injected will depend on the areas which are to be corrected.
• It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.

WARNINGS

• Confirm the integrity of the sterility protector before use.
• Confirm the expiry date on the product label.
• Do not re-use.
• Do not re-sterilise.
• For the needles (CE0086) :
- Used needles must be thrown away in the appropriate containers. Please consult the current directives in force to ensure their correct elimination.
- Never try to straighten a bent needle, throw it away and replace it.

STORAGE CONDITIONS

• Store between 2°C and 25°C.
• Fragile.

HYDRA FILL ® *SoftLine™ MAX*

Fragile.

To hold safe from the light.

Syringe.

Needle.

STERILE — Sterile, sterilised by moist heat.

STERILE R — Sterile, sterilised by radiation.

Manufacturer.

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