Juvéderm®
ULTRA 2

ALLERGAN

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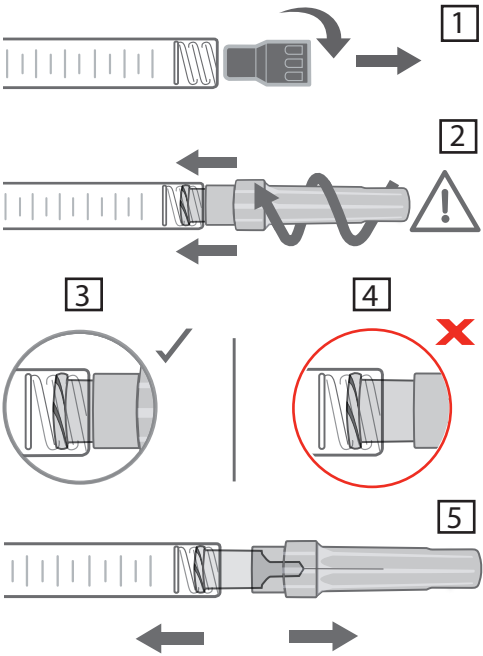
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COMPOSITION

Hyaluronic Acid gel	24 mg
Lidocaine hydrochloride	3 mg
Phosphate buffer pH 7.2 q.s.	1 mL

One syringe contains 0.55 mL of ***Juvéderm® ULTRA 2***.

DESCRIPTION

Juvéderm® ULTRA 2 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 two 0.55 mL ***Juvéderm® ULTRA 2*** syringes, 2 single-use 30G1/2" sterile needles to be used only for injecting ***Juvéderm® ULTRA 2***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm® ULTRA 2*** syringes are sterilised by moist heat.

The 30G1/2" needles are sterilised by radiation.

INDICATIONS

Juvéderm® ULTRA 2 is an injectable implant used for filling any medium-sized depressions of the skin via mid-dermis injection, as well as for lip definition.

The presence of lidocaine is meant to reduce the patient's pain during treatment.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm® ULTRA 2*** in the eyelids. The application of ***Juvéderm® ULTRA 2*** in the under-eye area is to be performed only by specialists specifically trained in this technique who have a sound knowledge of the physiology of this particular area.

• Do not inject into the blood vessels (intravascular).

• Do not overcorrect.

• ***Juvéderm® ULTRA 2*** must not be used in:

- Patients suffering from untreated epilepsy;
- Patients who tend to develop hypertrophic scarring;
- Patients with known hypersensitivity to hyaluronic acid;
- Patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics;
- Patients suffering from porphyria;
- Women who are pregnant or breastfeeding;
- Children.

• ***Juvéderm® ULTRA 2*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).

• ***Juvéderm® ULTRA 2*** should not be used simultaneously with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

• ***Juvéderm® ULTRA 2*** is indicated only for intra-dermal injections and injections in the mucous membrane of the lips.

• As a matter of general principle, injection of a medical device is associated with a risk of infection.

• There is no available clinical data (efficiency, tolerance) about injection of ***Juvéderm® ULTRA 2*** into an area which has already been treated with another filling product. It is recommended not to inject it in site which has been treated with a permanent implant.

• No clinical data is available regarding the efficiency and tolerance of ***Juvéderm® ULTRA 2*** injections in patients having a history of, or currently suffering from, autoimmune disease. The medical practitioner 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 also 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.

• There is no available clinical data concerning the tolerance of the ***Juvéderm® ULTRA 2*** 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 throats, acute rheumatic fever) shall be subjected to a dual test before any injection is administered. In the event of acute rheumatic fever with heart complications, it is recommended not to inject the product.

• Patients on anti-coagulation medication (anticoagulants, aspirin or nonsteroidal anti-inflammatory drugs) must be warned of the potential increased risks of haematomas and bleeding during injection.

• There is no data available regarding the safety of injecting greater amount than 20 mL of ***Juvéderm® ULTRA 2*** with lidocaine per 60 kg (130 lbs) body mass per year.

• The combination of ***Juvéderm® ULTRA 2*** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is inadvisable.

• ***Juvéderm® ULTRA 2*** should be used with caution in patients showing symptoms of cardiac conduction disorders.

• Please recommend that the patient not use any makeup during the 12 hours following the injection treatment and that any extended exposure to the sun, UV rays and temperatures below 0°C be avoided, as well as any sauna or hammam sessions during the two weeks following the injection treatment.

• If the needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle.

• Athletes should be made aware that this product contains an active principle that may produce a positive result in anti-doping tests.

• Medical practitioner must take into account the fact that this product contains lidocaine.

• The composition of this product is compatible with fields used for magnetic resonance imaging.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. ***Juvéderm® ULTRA 2*** should never therefore be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.

There is no known interaction with other local anaesthetics.

UNDESIRABLE EFFECTS

The patients must be informed that they are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. These include, but are not limited to:

• Inflammatory reactions (redness, oedema, erythema, etc.) which may be associated with itching or pain on pressure or both, 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 and/or lidocaine 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 side effect which develops, to their medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.

• Any other undesirable side effects associated with injection of ***Juvéderm® ULTRA 2*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE – POSOLOGY

• This product is designed to be injected into the dermis or the mucous membrane of the lips by an authorized medical practitioner in accordance with local applicable regulation. As precision is essential to a successful

treatment, the product must be used by medical practitioners who have undertaken specific training in injection techniques for filling.

• ***Juvéderm® ULTRA 2*** is to be used as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.

• Before starting treatment patients should be informed of the product's indications, 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 expiry date on the product label.

• Do not re-use. Sterility of this device can not be guaranteed if the device is re-used.

• Do not re-sterilise.

• For the needles (CE 0123 TSK Laboratory, Japan):

EC- Representative : Emergo Europe
Molenstraat 15
2513 BH The Hague (NL)

- Used needles must be thrown away in the appropriate containers. Do the same for the syringes. Please consult the current applicable directives 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.