Juvéderm
ULTRA PLUS™ XC

ALLERGAN

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ALLERGAN

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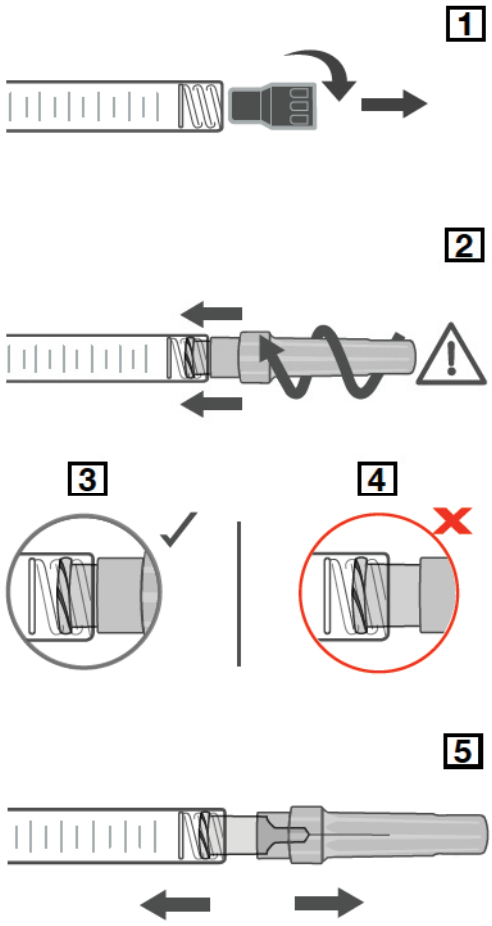
EMB761

Teoxane S.A.
Exhibit 1057



COMPOSITION

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

One syringe contains 0.8mL of ***Juvéderm ULTRA PLUS™ XC***.

DESCRIPTION

Juvéderm ULTRA PLUS™ XC 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 0.8mL ***Juvéderm ULTRA PLUS™ XC*** syringes, 4 single-use 27G1/2" sterile needles to be used only for injecting ***Juvéderm ULTRA PLUS™ XC***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm ULTRA PLUS™ XC*** syringes are sterilised by moist heat.
The 27G1/2" needles are sterilised by radiation.

INDICATIONS

Juvéderm ULTRA PLUS™ XC is an injectable implant used for filling mid and/or deep depressions of the skin via mid and/or deep dermis injection, as well as for lip definition and enhancement.
The presence of lidocaine is meant to reduce the patient's pain during treatment.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm ULTRA PLUS™ XC*** in the eyelids, crow's feet and glabellar region. The application of ***Juvéderm ULTRA PLUS™ XC*** 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 overcorrect.
• ***Juvéderm ULTRA PLUS™ XC*** must not be used in:
- Patients suffering from untreated epilepsy;
- Patients with known hypersensitivity to hyaluronic acid;
- Patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics;
- Patients suffering from porphyria;
• ***Juvéderm ULTRA PLUS™ XC*** must 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 PLUS™ XC*** must not be used in patients who tend to develop hypertrophic scarring.
• ***Juvéderm ULTRA PLUS™ XC*** must not be used in women who are pregnant or breastfeeding.
• ***Juvéderm ULTRA PLUS™ XC*** must not be used in children.
• ***Juvéderm ULTRA PLUS™ XC*** 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 PLUS™ XC*** 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 PLUS™ XC*** 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 PLUS™ XC*** 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 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.

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

• ***Juvéderm ULTRA PLUS™ XC*** 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 Turkish bath 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 practitioners 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 PLUS™ XC should therefore never 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 secondary 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 PLUS™ XC*** 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.

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