Juvéderm® VOLUMA®XC

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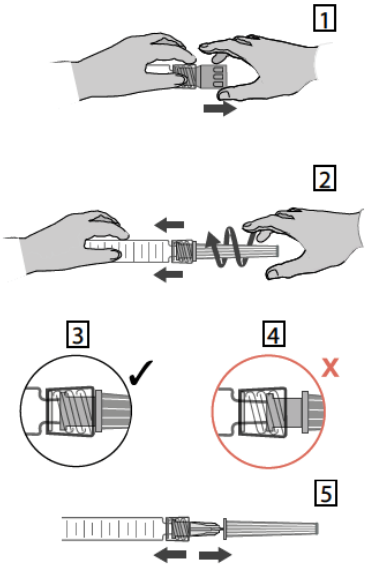

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Juvéderm® VOLUMA®XC

COMPOSITION

Hyaluronic acid gel	20 mg
Lidocaine hydrochloride	3 mg
Phosphate buffer pH 7.2 q.s.	1 mL

One syringe contains 2 mL of ***Juvéderm® VOLUMA®XC***.

DESCRIPTION

Juvéderm® VOLUMA®XC is a sterile, non pyrogenic and physiological solution of crosslinked hyaluronic acid which is not of animal origin.
The gel is presented in a pre-filled single use syringe .
Each box contains 1 syringe of ***Juvéderm® VOLUMA®XC***, 2 single-use 23G1" U.T.W (Ultra Thin Wall) needles and 2 single-use 18G, 70mm cannulae intended only for injecting ***Juvéderm® VOLUMA®XC***, an instruction leaflet, and a set of labels to ensure traceability.

STERILISATION

The content of the ***Juvéderm® VOLUMA®XC*** syringes are sterilised by moist heat.
The 23G1" U.T.W (Ultra Thin Wall) needles are sterilised by ethylene oxide.
The 18G, 70mm cannulae are sterilised by ethylene oxide.

INDICATIONS

Juvéderm® VOLUMA®XC is an injectable implant intended to restore volume of the face.
The presence of lidocaine is meant to reduce the patient's pain during treatment.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm® VOLUMA®XC*** in the periorbital area (eyelid, bags under the eyes, crow's feet), in the glabellar region or in the lips.
• Do not inject ***Juvéderm® VOLUMA®XC*** into blood vessels (intravascular).
• Do not over-correct.
• ***Juvéderm® VOLUMA®XC*** must not be used by:
- Patients suffering from untreated epilepsy;
- patients with a tendency to develop hypertrophic scars;
- patients with known hyper-sensitivity to hyaluronic acid;
- Patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics;
- Patients suffering from porphyria;
- women who are pregnant or breast-feeding;
- children.
• ***Juvéderm® VOLUMA®XC*** must not be used on areas showing skin problems such as inflammation and/or infections (acne, herpes, etc.).
• ***Juvéderm® VOLUMA®XC*** must not be used in immediate association with laser treatment, deep chemical peeling or a dermabrasion. In the case of superficial peeling, it is recommended not to inject it if it provokes a serious inflammatory reaction.

PRECAUTIONS FOR USE

• ***Juvéderm® VOLUMA®XC*** is not indicated for injections other than subcutaneous, upper periostea or into the deep dermis. The technique and the depth of the injection vary depending on the site of the treatment.
• ***Juvéderm® VOLUMA®XC*** is not recommended for intramuscular injections.
• As a matter of general principle, implantation of a medical device is associated with a risk of infection.
• There is no clinical data available regarding effectiveness and tolerance regarding the ***Juvéderm® VOLUMA®XC*** injection in an area having already been treated with another filling product. It is recommended to not inject it in site which has been treated with a permanent implant.
• There is no clinical data available regarding effectiveness and tolerance for the ***Juvéderm® VOLUMA®XC*** injection for patients with a previous history of or a declared auto-immune disease. The medical practitioner should therefore decide on the recommendation case by case, depending on the nature of the disease and its associated treatment and specific monitoring of these patients must be ensured. In particular, it is recommended to offer a double preliminary test to these patients and to not inject them if the disease is evolving.
• There is no available clinical data concerning the tolerance of the ***Juvéderm® VOLUMA®XC*** injection in patients presenting a history of severe multiple allergies or anaphylactic shock. The medical practitioner must therefore decide on the indication according to the individual case, depending on the nature of the allergy, and must ensure that there is individual surveillance of these patients who are at risk. In particular, the decision may be taken to propose a double test or preventive adapted treatment previously to any injection.
• Patients with a previous history of streptococcal disease (recurrent sore throat, acute rheumatic fever) must undergo a double test before all injections. Injection is not recommended in the case of acute rheumatic fever with cardiac localisation.
• 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.
• The combination of ***Juvéderm® VOLUMA®XC*** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is inadvisable.
• ***Juvéderm® VOLUMA®XC*** should be used with caution in patients showing symptoms of cardiac conduction disorders.
• Do not inject more than 2 mL per treatment site during each session.
• There is no data available regarding the safety of injecting greater amount than 20 mL of ***Juvéderm® VOLUMA®XC*** per 60 kg (130 lbs) body mass per year.
• Recommend to the patient that they do not wear make-up for 12 hours following the injection and to avoid lengthy exposure to the sun, to UV rays, temperatures below 0°C, as well as using a sauna or Turkish bath for two weeks.
• Recommend to the patient to avoid massaging the implantation site and/or putting pressure on it for a few days following the injection.
• If the needle or the cannula is blocked, do not increase the pressure on the plunger rod; stop the injection and replace the needle or the cannula.
• 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

There is a known incompatibility between sodium hyaluronate and quaternary ammonium salts such as benzalkonium chloride. It is therefore advisable to never put ***Juvéderm® VOLUMA®XC*** in contact

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Exhibit 1050

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Juvéderm® VOLUMA®XC

with these products, or with medical-surgical material treated with this type of product.

UNDESIRABLE EFFECTS

The patients must be informed that there are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. Amongst which: (non exhaustive list)

- Inflammatory reactions (redness, oedema, erythema, etc.) can appear after the injection which can be associated with itching or pain on pressure. These reactions can last for a week.
- Haematomas
- Indurations or nodules at the injection site
- Staining or discolouration in the injection area.
- Poor efficacy or poor filling / restoration effect.
- Cases of necroses in the glabellar region, abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid and/or lidocaine injections having been reported, is 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.
- The distributor and/or manufacturer must be informed about any other undesirable side effects linked to the ***Juvéderm® VOLUMA®XC*** injection.

METHOD OF USE-POSOLOGY

- This product is designed to be injected slowly into the deep dermis, subcutaneously, or in the upper periostea by an authorized medical practitioner in accordance with local regulation. Using the provided 23G1" U.T.W. (Ultra Thin Wall) needle or the 18G, 70mm cannula is recommended. Nevertheless, depending on the medical practitioner technique, it is also possible to use 21G1$^{1/2}$" / 22G1"T.W. (Thin Wall) sterile Luer Lock needles. If the medical practitioner feels that the extrusion force for injecting through the 23G1" U.T.W. (Ultra Thin Wall) needle is too high, a 21G1$^{1/2}$" or a 22G1" T.W. (Thin Wall) needle is recommended.
- ***Juvéderm® VOLUMA®XC*** 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. The technical nature of this is essential to the treatment's success, so this product must be used by medical practitioners who have undergone specific training in injection techniques for volume restoration. Excellent knowledge of the anatomy and physiology of the treatment area is required.
- Before undertaking the treatment, the patient should be informed about the device's indications, its contra-indications, its incompatibilities and its potential side-effects.
- Before the injection, disinfect the treatment area rigorously.
- It is possible, if necessary, to use local or local-regional anaesthetic. In this case, the instructions for using these products must be followed.
- Remove tip cap by pulling it straight off the syringe as shown in (fig. 1).

Hold the syringe body, firmly insert the cannula or the needle provided in the package (fig. 2).

Firmly attach the cannula or the needle turning it gently clockwise as shown fig.2 until you get it well engaged into the syringe Luer Lock system.
Check the needle visually according to figs. 3 and 4.
Holding the syringe body in one hand and the cannula/needle cap in the other, pull the two hands in opposite direction to remove it, as shown in fig.5.
Inject slowly.
Failure to comply with these precautions could cause a disengagement of the needle or of the cannula and/or product leakage at luer-lock level.

- The quantity to inject depends on the area to be corrected.
- After the injection, it is important to massage the treated area to make sure that the product is evenly distributed.

WARNINGS

- Check that the sterility protector is intact before use.
- Check the expiry date on the labelling.
- Do not reuse. Sterility of this device can not be guaranteed if the device is re-used.
- Do not resterilise.
- For the needles (CE 0197) and cannulae (CE 1014):
  - Used needles and cannulae must be properly disposed of. Do the same for the syringes. Please refer to the current, applicable regulations to ensure their correct elimination.
  - Never try to straighten a bent needle or cannula; throw it away and use a new one.
- ***Juvéderm® VOLUMA®XC*** gel must be used prior to the expiration date printed on the package.

STORAGE CONDITIONS

- Preserve between 2°C and 25°C.
- Fragile.
- Shelf life: 2 years

Juvéderm®VOLUMA®XC contains trace amounts (<2ppm) of the cross linking agent butanediol diglycidyl ether (BDDE).

POISON SCHEDULES

S4 in all Australian states.

LATEX	Do not contain elastomer-rubber latex.
2	Do not re-use.
	Attention, see instructions for use.
2°C 25°C	Temperature limit.
	Do not use if the package is damaged.
LOT	Batch No.
	Use by.
	Manufacturer.
	Fragile.
	To hold safe from the light.
	Syringe.
	Needle.
	Cannula.
STERILE	Sterile, sterilised by moist heat.
STERILE EO	Sterile, sterilised by ethylene oxide.
REF	Reference.

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