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Juvéderm®

VOLUMA®

WITH LIDOCAINE

2 x 1mL

This document contains:
- 1 Directions for Use
- 2 Patient Implant Cards

Allergan Aesthetics

20083910
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Manufacturer:
ALLERGAN
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FRANCE

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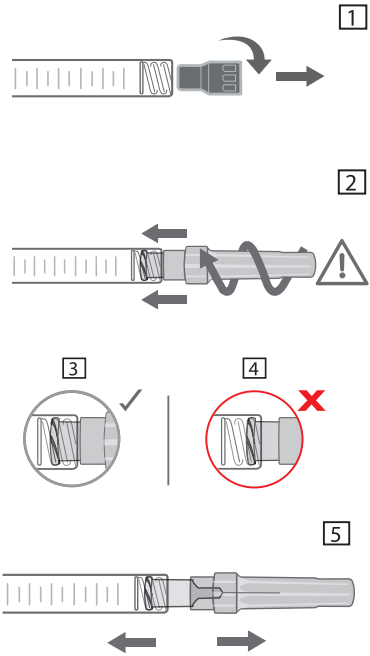
Only for professional use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COMPOSITION

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

One syringe contains 1 mL of ***Juvéderm® VOLUMA® with Lidocaine***.

DESCRIPTION

Juvéderm® VOLUMA® with Lidocaine is a sterile, pyrogen-free physiological solution of cross-linked hyaluronic acid (HA) which is not of animal origin. The gel is presented in a graduated, pre-filled, disposable syringe. Each box contains two 1mL ***Juvéderm® VOLUMA® with Lidocaine*** syringes, 4 single- use 27G/1/2" sterile needles to be used only for injecting ***Juvéderm® VOLUMA® with Lidocaine***, an instruction leaflet, and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm® VOLUMA® with Lidocaine*** syringes are sterilised by moist heat. The 27G1/2" needles are sterilised by radiation.

INDICATIONS

- ***Juvéderm® VOLUMA® with Lidocaine*** 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® with Lidocaine*** in the periorbital area (eyelid, under- eye area, crow's feet) in the glabellar region or in the lips.
- Do not inject ***Juvéderm® VOLUMA® with Lidocaine*** into the blood vessels (intravascular). Intravascular injection may lead to embolisation, occlusion of the vessels, ischaemia or infarction.
- Do not overcorrect.
- ***Juvéderm® VOLUMA® with Lidocaine*** must not be used in:

- patients suffering from untreated epilepsy;
- patients who tend to develop hypertrophic scarring;
- patients with known hypersensitivity to hyaluronic acid and/or to gram positive bacterial proteins as hyaluronic acid is produced by *Streptococcus* type bacteria;
- patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics;
- patients suffering from porphyria;
- women who are pregnant or breastfeeding;
- children.

- ***Juvéderm® VOLUMA® with Lidocaine*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).
- ***Juvéderm® VOLUMA® with Lidocaine*** 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® VOLUMA® with Lidocaine*** is not indicated for injections other than subcutaneous, upper-periostea or into the deep dermis. The technique and depth of the injection vary depending on the area to be treated.
- Health care professionals must take into account the fact that this product contains lidocaine.
- ***Juvéderm® VOLUMA® with Lidocaine*** is not intended for use in breast augmentation/ reconstruction.
- ***Juvéderm® VOLUMA® with Lidocaine*** is not recommended for intramuscular injections.
- As a matter of general principle, injection of a medical device is associated with a risk of infection. Standard precautions

associated with injectable materials should be followed.

- There is no available clinical data about injection of ***Juvéderm® VOLUMA® with Lidocaine*** into an area which has already been treated with a non–Juvéderm dermal filler.
- It is recommended not to inject into a site which has been treated with a permanent implant.
- There is no available clinical data regarding the efficiency and tolerance of ***Juvéderm® VOLUMA® with Lidocaine*** injection into the non-midline areas of the nose, nasal tip and the post-surgical/traumatic nose. Medical practitioner should be aware of the increased risk of vascular compromise/injury in the nasal tip due to the limited space available to accommodate injected product and in the post-surgical/traumatic nose due to scar and/or anatomic disruption.
- No clinical data is available regarding the efficiency and tolerance of ***Juvéderm® VOLUMA® with Lidocaine*** injections in patients having a history of, or currently suffering from, autoimmune disease or autoimmune deficiency or being under immunosuppressive therapy. 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 skin testing for hypersensitivity and to refrain from injecting the product if the disease is active.
- There is no available clinical data regarding the tolerance of the ***Juvéderm® VOLUMA® with Lidocaine*** injection in patients presenting a history of severe and/or multiple allergies. 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 skin testing for hypersensitivity or suitable preventive treatment prior to any injection.

In case of history of anaphylactic shock, it is recommended not to inject the product.

- Patients showing a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to skin testing for hypersensitivity 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 or using substances that can prolong bleeding (warfarin, acetylsalicylic acid, nonsteroidal anti-inflammatory drugs or other substances known to increase coagulation time such as herbal supplements with garlic or ginkgo biloba, etc.) must be warned of the potential increased risks of bleeding and haematomas during injection.
- Do not inject more than 2 mL per treatment area during each session.
- There is no data available regarding the safety of injecting greater amount than 20 mL of Juvéderm dermal fillers per 60 kg (130 lbs) body mass per year.
- Due to presence of lidocaine, the combination of ***Juvéderm® VOLUMA® with Lidocaine*** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is not recommended.
- Due to presence of lidocaine, ***Juvéderm® VOLUMA® with Lidocaine*** 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.
- 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® VOLUMA® with Lidocaine*** 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 there 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 and/or pain on pressure and/or paraesthesia, 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 might be observed, especially when HA dermal filler is injected too superficially and/or in thin skin (Tyndall effect).
- Poor effect or poor filling/restoration effect.
- Rare but serious adverse events associated with intravascular injection of dermal fillers in the face and tissue compression have

been reported and include temporary or permanent vision impairment, blindness, cerebral ischaemia or cerebral haemorrhage, leading to stroke, skin necrosis and damage to underlying structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in the vision, signs of stroke, blanching of the skin or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate medical practitioner specialist should an intravascular injection occur. Abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid and/or lidocaine injections have also 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® VOLUMA® with Lidocaine*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE-POSOLOGY

- This product is designed to be injected into the deep dermis, subcutaneously or in the upper periostea by an authorised health care professional in accordance with local applicable regulation. In order to minimise the risks of potential complications and as precision is essential to a successful treatment, the product should be only used by health care professionals who have appropriate training, experience and who are knowledgeable about the anatomy at and around the site of injection.

Use of the supplied 27G1/2" needle is recommended. However, depending on the health care professional's preferred injection technique, it is possible to use a 25G sterile cannula (please refer to the list hereunder). Choice of cannula length is determined by the user according to his/her injection technique.

Material Number	Description
SCG-25038	TSK STERiGLIDE 25G 38mm
SCG-25050	TSK STERiGLIDE 25G 50mm

- Contra-indications, Method of use, Precautions for use and Warnings defined for the needle in this leaflet apply also to the cannula referenced above if used with this product.
- ***Juvéderm® VOLUMA® with Lidocaine*** 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.
- Prior to treatment, health care professionals shall inform their patients about the product's indications, contra-indications, incompatibilities and potential undesirable effects/risks associated with dermal fillers injection and ensure that patients are aware of signs and symptoms of potential complications.
- 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.

Prior to injecting, depress the plunger rod until the product flows out of the needle.

Inject slowly and apply the least amount of pressure necessary.

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

Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level and/or increase the risk of vascular compromise.

- After needle insertion and before injection, it is recommended to withdraw slightly the plunger to aspirate and verify the needle is not intravascular.
- If immediate blanching occurs at any time during the injection, the injection should be stopped and appropriate action taken such as massaging the area until its return to a normal colour.
- The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique. The amount injected will depend on the areas which are to be corrected based on the experience of the health care professional.
- Do not overcorrect as injection of an excessive volume can be at the origin of some side effects such as tissue necrosis and oedema.
- A touch up (for achieving optimal correction) and/or a repeat (for maintaining optimal correction) treatment with

Juvéderm® VOLUMA® with Lidocaine might be required.

- It is recommended to wait until side effects are resolved (with a minimal interval of 2 weeks) between two injections.
- It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.

WARNINGS

- Check the expiry date on the product label.
- In the event that the content of the syringe shows signs of separation and/or appears cloudy, do not use the syringe.
- Do not re-use. Sterility of this device cannot be guaranteed if the device is re-used.
- Do not re-sterilise.
- For the needles (CE 0123):
  - 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.
- ***Juvéderm® VOLUMA® with Lidocaine*** gel must be used prior to the expiration date printed on the package.

STORAGE CONDITIONS

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

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

POISON SCHEDULES

S4 in all Australian states.

- Does not contain elastomer-rubber latex

- *Single use*

- Syringe

- Date of manufacture

- Do not use if package is damaged and consult *instructions for use*

- Consult *instructions for use* or consult electronic *instructions for use*

- Use-by date

- Sterilized using irradiation

• Batch code

• Temperature limit

• Fragile, handle with care

• Needle

• Keep away from sunlight

• Sterilized using steam or dry heat•

• Catalogue number

• Manufacturer

2 Patient Implant Cards
to be provided to patients injected with ***Juvéderm® VOLUMA® with Lidocaine*** are provided on the next page

Please ensure you add the Batch/Lot number to the Patient Implant Card prior to providing to the patient.

Please note that additional space has also been provided on the reverse of the Patient Implant Card for you to insert the name of the injecting doctor and/or treatment clinic.

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J. VOLUMA W LIDO
LOT:
EXP:
1 x 1.0mL

Refer to Patient Information Leaflet:

or https://www.allerganaesthetics.com.au/our-products/juvederm-voluma-with-lidocaine

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