Juvéderm®

VOLBELLA®

WITH LIDOCAINE

2 x 1mL

This document contains:
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- 2 Patient Implant Cards

Allergan Aesthetics

20075253
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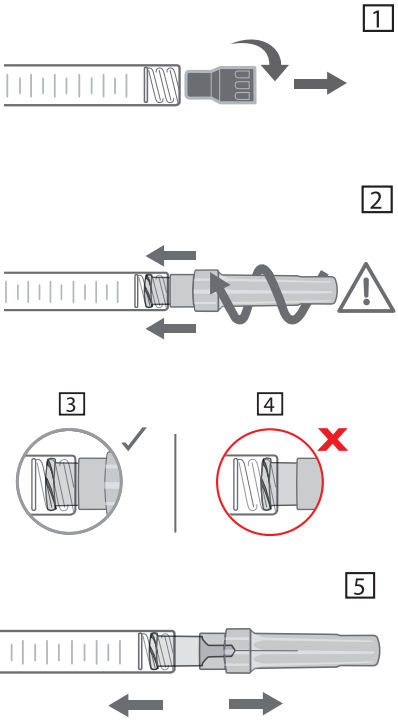
Only for professional use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COMPOSITION

Hyaluronic acid gel	15 mg
Lidocaine (lignocaine) hydrochloride monohydrate	3 mg
Phosphate buffer pH 7.2 q.s.	1 mL

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

DESCRIPTION

Juvéderm® VOLBELLA® 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® VOLBELLA® with Lidocaine*** syringes, 4 single-use 32G1/2" sterile needles to be used only for injecting ***Juvéderm® VOLBELLA® with Lidocaine***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm® VOLBELLA® with Lidocaine*** syringes are sterilised by moist heat.

The 32G1/2" needles are sterilised by radiation.

INDICATIONS

• ***Juvéderm® VOLBELLA® with Lidocaine*** is an injectable implant intended for the treatment of any fine lines and medium-sized skin depressions due to conditions such as premature ageing.

• ***Juvéderm® VOLBELLA® with Lidocaine*** can also be used for enhancement and pouting of the lips.

• ***Juvéderm® VOLBELLA® with Lidocaine*** is intended to be used via superficial or mid-dermis injection or lips mucosa injection by an authorised health care professional. For the treatment of the infraorbital skin depressions (also known as tear trough area), it is recommended to inject in the submuscular /

pre-periosteal plane.
• The presence of lidocaine is meant to reduce the patient's pain during treatment.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm® VOLBELLA® with Lidocaine*** into the eyelids. The application of ***Juvéderm® VOLBELLA® with Lidocaine*** in the infraorbital area is reserved to appropriately qualified health care professionals specifically trained in the appropriate injection technique and with a sound knowledge of the anatomy and physiology for this particular area.
• Do not inject into the blood vessels (intravascular). Intravascular injection may lead to embolisation, occlusion of the vessels, ischaemia or infarction.
• Do not overcorrect.
• ***Juvéderm® VOLBELLA® 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;
- women who are pregnant or breastfeeding;
- patients suffering from porphyria;
- children.
• ***Juvéderm® VOLBELLA® with Lidocaine*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).
• ***Juvéderm® VOLBELLA® 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.

WARNINGS

• The product must not be injected into blood vessels. Introduction of ***Juvéderm® VOLBELLA® with Lidocaine*** injectable gel into the vasculature may lead to embolisation, occlusion of the vessels, ischaemia or infarction. Take extra care when injecting soft-tissue fillers, for example, after insertion of the needle, and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly, and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft-tissue fillers in the face 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 facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in 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 health care professional specialist should an intravascular injection occur.

• If immediate blanching occurs, the injection should be stopped and the area massaged until it returns to a normal colour. Blanching may represent a vessel occlusion. If normal skin colouring does not return, do not continue with the injection. Treat in accordance with clinical guidelines which include hyaluronidase injection.

• Do not overcorrect as injection of an excessive volume can be at the origin of some side effects such as tissue necrosis and oedema.

PRECAUTIONS FOR USE

• ***Juvéderm® VOLBELLA® with Lidocaine*** is indicated only for intra-dermal injections for fine lines and moderate skin depressions, injections in mucous membrane of the lips and submuscular/pre-periosteal injections for tear trough/infraorbital area.

• Health care professionals must take into account the fact that this product contains lidocaine.

• ***Juvéderm® VOLBELLA® with Lidocaine*** is not intended for use in breast augmentation/ reconstruction.

• 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® VOLBELLA® 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.

• No clinical data is available regarding the efficiency and tolerance of ***Juvéderm® VOLBELLA® 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® VOLBELLA® 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.

• No clinical data is available concerning the injection in the infraorbital region of ***Juvéderm® VOLBELLA® with Lidocaine*** in patients with a pre-existing tendency for infraorbital oedema. The medical practitioner should therefore consider the patient's history and infraorbital anatomy and physiology in evaluating whether the patient is a candidate for treatment. These patients must be warned of the potential increased risk of prolonged oedema that may occur following infraorbital treatment.

• 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.

• 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® VOLBELLA® with Lidocaine*** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta- blockers, etc.) is not recommended.

• Due to presence of lidocaine, ***Juvéderm® VOLBELLA® with Lidocaine*** should be used with caution in patients showing symptoms of cardiac conduction disorders.

• Please inform the patient prior to treatment regarding the risks and side effects of the treatment. Early identification of complications is vital. Ensure that patients are aware of signs and symptoms of potential complications. Pre and post intervention vision assessment may be considered as appropriate in the opinion of the injecting health care professional following assessment of the individual patient.

• Patients may experience late onset adverse events with use of dermal fillers, including ***Juvéderm® VOLBELLA® with Lidocaine***. Refer to Adverse Effects section for details.

• Please instruct the patient to promptly report to their health care professional any evidence of problems possibly associated with the use of ***Juvéderm® VOLBELLA® with Lidocaine***.

• 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® VOLBELLA® 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.

ADVERSE 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.

The most common side effects include temporary reactions at the treatment site such as swelling, non inflammatory nodule, inflammatory reaction (such as acne, induration and herpes), allergic reaction (such as urticaria, dermatitis, hypersensitivity), haematomas, pain/tenderness, redness and discolouration. These side effects are consistent with other facial injection procedures.

Other side effects can occur such as unsatisfactory results after treatment, device migration, inflammatory nodule, cyst, tissue damage, necrosis, infection, autoimmune disorder, vision disorder/loss, vascular occlusion, stroke, neurological symptoms (such as headache, dizziness, paraesthesia), cardiac complications (such arrhythmia).

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. 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.
• In many cases, the symptoms are resolved without treatment, however in some cases the adverse effects last for 30 days or longer. Based on the individual patient, the healthcare professionals can treat the adverse effect with the most appropriate treatment available.
• Adverse reactions should be reported to Allergan Aesthetics at 1800 252 224 and/or to TGA.

METHOD OF USE - POSOLOGY

• This product is designed to be injected into the dermis, in the mucous membrane of the lips or in the submuscular / pre-periosteal plane for infraorbital area 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 and experience in injection techniques for filling skin depression, face contouring and volume restoration. They have to be knowledgeable about the anatomy and physiology at and around the site of injection.
• Use of the supplied 32G1/2" needle is recommended. However, depending on the health care professional's preferred injection technique, it is possible to use:
- a 30G sterile cannula (please refer to the list hereunder). Choice of cannula length is determined by the user according to his/her injection technique.
- a 30G1/2" sterile needle

Material Number	Description
94323/ HPC30019ACSH	Easyflow System-20* cannula 30G x 19mm.
94324/ HPC30025ACSH	Easyflow System-20* cannula 30G x 25mm.
HPC-30013A	30G1/2" TSK Hypodermic needle

• 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® VOLBELLA® 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 adverse 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.

• Check the expiry date on the product label.

• ***Juvéderm® VOLBELLA® with Lidocaine*** gel must be used prior to the expiration date printed on the package.

• In the event that the content of the syringe shows signs of separation and/or appears cloudy, do not use the syringe.

• 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.

• Never try to straighten a bent needle; throw it away and replace it.

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.

• For injections in the infraorbital area, the following technique is recommended:

- Insert the needle below the orbital rim perpendicular to the skin surface and advance until contacting the periosteum.

- Slowly inject in the submuscular/ pre-periosteal plane along the infraorbital hollow with the needle using a depot injection technique. Reposition the needle as needed in between depot injections, always ensuring that the needle is directly below the muscle and aspirating prior to injection to ensure the needle tip is not within a vessel.

- If a cannula is used instead of a needle, use the introducer needle to create an insertion point for the cannula below the orbital rim and inject using a retrograde tunneling technique.

• 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.
• 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.
• A touch-up (for achieving optimal correction) and/or a repeat (for maintaining optimal correction) treatment with ***Juvéderm® VOLBELLA® 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.

STORAGE CONDITIONS
• Store between 2°C and 25°C.
• Fragile.
• Shelf life: 2 years

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

POISON SCHEDULES
S4 in all Australian states.

• Batch code

• Fragile, handle with care

• Temperature limit

• Needle

• Do not contain elastomer-rubber latex

•Do not re-use

• Syringe

• Date of manufacture

• Consult instructions for use or electronic instructions for use

• Use-by date

• Sterilized using irradiation

• Sterilized using steam or dry heat

• Catalogue number

• Manufacturer

• Do no use if package is damaged and consult instructions for use

• Keep away from sunlight

2 Patient Implant Cards
to be provided to patients injected with ***Juvéderm® VOLBELLA® 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.

Juvéderm

VOLBELLA®

WITH LIDOCAINE

VOLBELLA W LIDO
LOT:
EXP:
1 x 1.0mL

Refer to Patient Information Leaflet:

or www.allerganaesthetics.com.au /juvederm-volbella-with-lidocaine

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VOLBELLA®

WITH LIDOCAINE

VOLBELLA W LIDO
LOT:
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