



Juvéderm<sup>®</sup>  
VOLITE™

2 x 1mL

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

**Allergan**  
**Aesthetics**  
an AbbVie company

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**Allergan**

**Manufacturer:**

ALLERGAN  
Route de Promery  
Zone Artisanale de Pré-Mairy  
PRINGY 74370 ANNECY-FRANCE

**Australian Distributor:**

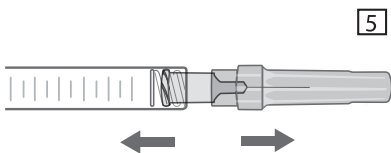
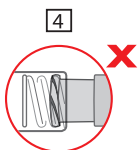
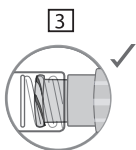
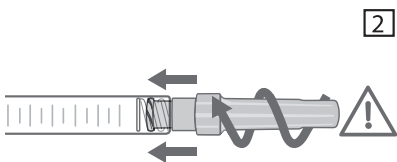
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Only for professional use





## **COMPOSITION**

Hyaluronic Acid gel	12.0 mg
Lidocaine (lignocaine) hydrochloride monohydrate	3.0 mg
Phosphate buffer pH 7.2 q.s.	1 mL (or g)

One syringe contains 1 mL of **Juvéderm® VOLITE™**.

## **DESCRIPTION**

**Juvéderm® VOLITE™** 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 1 mL **Juvéderm® VOLITE™** syringes, 4 single-use 32G1/2" sterile needles to be used only for injecting **Juvéderm® VOLITE™**, an instruction leaflet and a set of labels in order to ensure traceability.

## **STERILISATION**

The contents of the **Juvéderm® VOLITE™** syringes is sterilised by moist heat. The 32G1/2" needles are sterilised by radiation.

## **INDICATIONS**

- **Juvéderm® VOLITE™** is an injectable implant used for the treatment, by filling, of superficial cutaneous depressions such as fine lines and for additional improvement of skin quality attributes such as hydration and elasticity, via intradermal injection.
- The presence of lidocaine is meant to reduce the patient's pain during treatment.

## **CONTRA-INDICATIONS**

- Do not inject **Juvéderm® VOLITE™** in the eyelids.
- 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® VOLITE™** 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;
  - Patients under 18 years of age.
- **Juvéderm® VOLITE™** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).
- **Juvéderm® VOLITE™** 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® VOLITE™** is indicated only for intra-dermal injections.
- Injection of volume greater than 8.0 mL of **Juvéderm® VOLITE™** injectable gel per treatment session has not been studied.
- The efficacy and safety of **Juvéderm® VOLITE™** has been clinically studied only in the face and neck.
- Health care professionals must take into account the fact that this product contains lidocaine.
- **Juvéderm® VOLITE™** 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 shall be followed.
- There is no available clinical data about

injection of **Juvéderm® VOLITE™** into an area which has already been treated with a non-ALLERGAN 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® VOLITE™** 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 concerning the tolerance of **Juvéderm® VOLITE™** 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 a skin test 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 a skin test 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 amounts than 20 mL of ALLERGAN dermal fillers per 60 kg (130 lbs) body mass per year.
- Due to the presence of lidocaine, the combination of **Juvéderm® VOLITE™** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is not recommended.
- Due to the presence of lidocaine, **Juvéderm® VOLITE™** 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® VOLITE™** 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**

Physicians must inform the patient that there are potential side effects and/or incompatibilities associated with implantation of this device, which may occur immediately or may be delayed. The following events and reactions have been observed with the device or similar products:

- Angioedema, bacterial infections, bleeding, burning, discolouration, discomfort, haematoma/bruising, herpes reactivation, induration (including firmness), inflammation, itching (including irritation), loss/lack of correction (poor effect or weak filling effect), migration, nodules (inflammatory and non inflammatory, including beading/lumpiness/implant site mass), numbness/paraesthesia, pain (including tenderness), puncture marks, redness (including erythema), scar, swelling (oedema), teleangiectasia, vasospasm / vasovagal reaction during injection.

- 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.

- Herpes virus reactivations may be provoked in rare cases by direct damage of neuronal axons by the needle or by tissue manipulation and inflammatory reaction after filler injection. The dissection of the subepidermal plane by fanlike needle use may increase the incidence of local adverse events.
- 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). Furthermore, too superficial placement of the filler or an uneven distribution of the injected product may lead to visible, pale nodules in the skin.
- Patients must inform their physician as soon as possible about any inflammatory reactions persisting for more than one week or any other occurring secondary effect. The physician should treat these side effects appropriately.
- Any other undesirable side effects associated with injection of the device must be reported to the distributor and/or to the manufacturer.

### **METHOD OF USE - POSOLOGY**

- This product is designed to be injected intra-dermally 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 treating superficial cutaneous depressions. They have to be knowledgeable about the anatomy 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 32G3/16" TSK needle (reference PRE-32004).  
Choice of needle length is determined by the user according to his/her injection technique.

- Contra-Indications, Method of use, Precautions for use and Warnings defined for the needle in this leaflet apply also to the needle referenced above if used with this product.

- **Juvéderm® VOLITE™** 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. In particular, for large surface treatment, the whole area shall be considered (e.g. full face).

- 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 slightly withdraw 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) with **Juvéderm® VOLITE™** might be required. Treatment effects will be temporary and repeat-treatment will be required to maintain optimal results.
- 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 a 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® VOLITE™** 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® VOLITE™** 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



- Single use



- Syringe



- Date of manufacture

LOT

• Batch code



• Temperature limit



• Fragile, handle with care



• Needle





• Do not use if package is damaged



• Attention; see instructions for use



• Use-by date



• Sterilized using irradiation



• Keep away from sunlight



• Sterilized using steam or dry heat



• Catalogue number



• Manufacturer