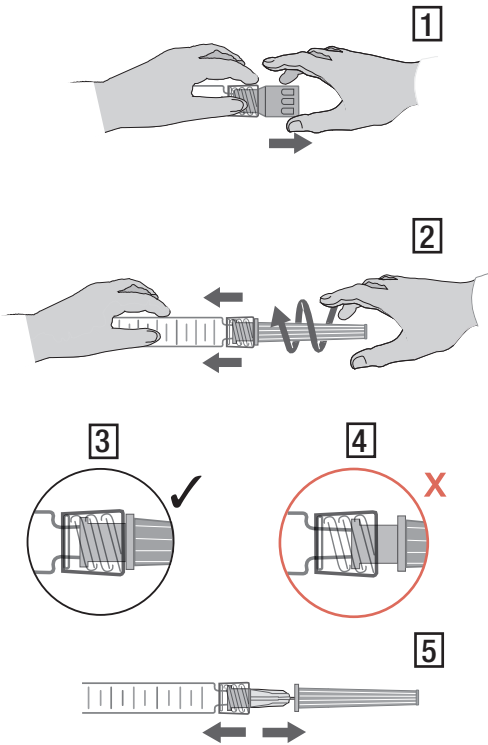




72067ED10X



**Manufacturer: ALLERGAN**  
Route de Promery  
Zone Artisanale de Pré-Mairy  
74370 PRINGY-FRANCE

**Distributed by: ALLERGAN**  
Australia Pty Ltd  
GORDON NSW 2072

**CE**  
0459  
(2008)



#### COMPOSITION

Crosslinked hyaluronic acid 20 mg  
Phosphate buffer pH 7.2 q.s. 1 g  
One syringe contains 2 ml of **Juvéderm™VOLUMA™**.

#### DESCRIPTION

**Juvéderm™VOLUMA™** 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™**, 2 single-use 23G1" U.T.W (Ultra Thin Wall) needles and 2 single-use 18G, 70mm cannulae intended only for injecting **Juvéderm™VOLUMA™**, an instruction leaflet, and a set of doctor/patient labels to ensure traceability.

#### STERILISATION

The contents of the **Juvéderm™VOLUMA™** 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™** is an injectable implant intended to restore volume of the face.

#### CONTRA-INDICATIONS

- Do not inject **Juvéderm™VOLUMA™** in the periorbital area (eyelid, bags under the eyes, eye wrinkles) and in the glabellar region.
- Do not inject **Juvéderm™VOLUMA™** into blood vessels (intravascular).
- Do not over-correct.
- **Juvéderm™VOLUMA™** must not be used by:
  - patients with a tendency to develop hypertrophic scars;
  - patients with known hyper-sensitivity to hyaluronic acid;
  - women who are pregnant or breast-feeding;
  - children.
- **Juvéderm™VOLUMA™** must not be used on areas showing skin problems such as inflammation and/or infections (acne, herpes, etc.).
- **Juvéderm™VOLUMA™** 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™** is not indicated for injections other than subcutaneous, upper periosteal or into the deep dermis. The technique and the depth of the injection vary depending on the site of the treatment.
- There is no clinical data available regarding effectiveness and tolerance regarding the **Juvéderm™VOLUMA™** 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™** injection for patients with a previous history of or a declared auto-immune disease. The doctor 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™** injection in patients presenting a history of severe multiple allergies or anaphylactic shock. The doctor 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 rheumatoid arthritis) must undergo a double test before all injections. Injection is not recommended in the case of acute rheumatoid arthritis with cardiac localisation.
- Patients undergoing anti-coagulant treatment must be warned of the increased risks of haematomas and bleeding during injection. For the same reason, it is recommended to avoid taking aspirin or vitamin C in high doses the week before the injection.



- Do not inject more than 2 ml per treatment site during each session.
- 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.
- Screw the needle firmly onto the syringe and then remove its protective cap by turning it in the same direction as that used to tighten the needle.
- If the needle is blocked, do not increase the pressure on the plunger rod; stop the injection and replace the needle.

### 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™** in contact with these products, or with medical-surgical material treated with this type of product.

### UNDESIRABLE EFFECTS

The doctor must inform the patient that there are potential side effects linked to this procedure, which can be either immediate or 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
- Coloration 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 injections having been reported, is advisable to take these potential risks into account.
- The patient must inform the doctor about persistent inflammatory reactions lasting more than one week or the appearance of any other secondary reactions as soon as possible. The doctor must treat this appropriately.
- The distributor and/or manufacturer must be informed about any other undesirable side effects linked to the **Juvéderm™VOLUMA™** injection.

### METHOD OF USE-POSOLGY

- This device is intended to be injected slowly into the deep dermis, subcutaneously or in the upper periosteum by a doctor. Using the provided 23G1" U.T.W. (Ultra Thin Wall) needle or the 18G, 70mm cannula is recommended. Nevertheless, depending on the doctor's technique, it is also possible to use either 21G1<sup>1/2</sup>" / 22G1" T.W. (Thin Wall) sterile Luer Lock needles or a smooth 19G, 70mm sterile Luer Lock cannula. If the doctor feels that the extrusion force for injecting through the 23G1" U.T.W. (Ultra Thin Wall) needle is too high, a 21G1<sup>1/2</sup>" or a 22G1" T.W. (Thin Wall) needle is recommended.
- 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 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
- Do not resterilise
- For the needles (CE0318) and cannulae (CE1014):
  - Used needles and cannulae must be properly disposed of. 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™** gel must be used prior to the expiration date printed on the package. **Juvéderm™VOLUMA™** gel has a shelf life of 24 months when stored between 2°C and 25°C.

### STORAGE CONDITIONS

- Preserve between 2°C and 25°C.
- Fragile.

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

### POISON SCHEDULES

S4 in all Australian states.



Do not contain Latex.



Do not re-use.



Attention, see instructions for use.



Temperature limit.



Do not use if the package is damaged.



Batch No.



Use by.



Manufacturer.



Fragile.



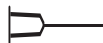
To hold safe from the light.



Syringe.



Needle.



Cannula.



Sterile, sterilised by moist heat.



Sterile, sterilised by ethylene oxide.



Reference.