
DATA SHEET

NAME OF MEDICINE

Juvéderm[®] *VOLUMA*[®] XC 20mg/mL injectable gel implant

Presentation

Juvéderm[®] *VOLUMA*[®] XC injectable gel implant is a sterile pyrogen-free physiological solution of cross-linked hyaluronic acid which is not of animal origin. The gel is presented in a graduated pre-filled, single use syringe.

Uses

Actions

Juvéderm[®] *VOLUMA*[®] XC consists of hyaluronic acid (HA) a polysaccharide naturally present in the body at different concentrations, especially in the skin, muscular system and skeleton.

The concentration of HA in the skin naturally decreases with age. The result is a decrease in the skin's elasticity and ability to hold water. This renders the dermis less voluminous and increases the tendency of the skin to form wrinkles.

In its natural unmodified state, implanted exogenous HA rapidly degrades quickly *in situ*. It is cross-linked to enhance *in vivo* persistence when used as dermal filler. By chemically cross-linking molecules of HA more stable macromolecules are formed which have the same biocompatibility as native HA.

Because HA cannot penetrate into the skin when applied topically HA derivatives are injected into the dermal tissue to provide a space-occupying viscoelastic matrix of the connective tissue.

Indications

Juvéderm[®] *VOLUMA*[®] XC injectable gel implant intended to restore the volume of the face. The presence of lidocaine reduces patient pain during the treatment.

Dosage and Administration

Juvéderm[®] *VOLUMA*[®] XC contains 20mg/mL cross-linked hyaluronic acid in a physiological buffer.

Juvéderm[®] *VOLUMA*[®] XC is designed to be injected slowly into the deep dermis, subcutaneously or in the upper periosteum by a practitioner. The technique used for this is essential in the success of treatment and therefore *Juvéderm*[®] *VOLUMA*[®] XC must be used by doctors who have received specific training in the injection technique for volume restoration.

Before starting treatment patients should be informed of the indications for the device, its contraindications, incompatibilities and potential undesirable effects.

The area to be treated should be disinfected thoroughly prior to the injection.

Remove tip cap by pulling it straight off the syringe. Hold the syringe body firmly push the cannula or the needle provided in the package and attach the cannula or needle turning it gently clockwise until it is well engaged into the syringe luer lock system. Next, remove the protective cap by holding the body of the syringe in one hand, the protective cap in the other and pulling the two hands in opposite directions. Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level.

The amount injected will depend on the area to be corrected.

It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.

Contraindications

- Do not inject *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel in the periorbital area (eye lids, bags under the eyes, crow's feet) and in the glabellar region or in the lips.
- Do not inject *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel into the blood vessels (intravascular).
- Do not overcorrect.
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used in patients who are known to be hypersensitive to hyaluronic acid and hypersensitive to lidocaine or to amide-type local anaesthetics
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used in patients suffering from untreated epilepsy
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used in patients who are known to be hypersensitive to hyaluronic acid.
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used in patients suffering from porphyria
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used in women who are pregnant or breast feeding, or in children.
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used in areas showing skin problems such as inflammation and/or infections (e.g. acne, herpes, etc).
- *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must not be used simultaneously with laser therapy, chemical peeling or dermabrasion.

Warnings and Precautions

Juvéderm[®] *VOLUMA*[®] *XC* injectable gel is not indicated for injections other than subcutaneous, upper periosteum or into the deep dermis.

- *Juvéderm*[®] *VOLUMA*[®] *XC* is not recommended for intramuscular injections.
- There is no available clinical data regarding effectiveness and tolerance about injection of *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel into an area which has already been treated with another filling product.
- There is no available clinical data (efficiency, tolerance) about injection of *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel in patients with a past history of or a declared autoimmune disease. The practitioner should therefore decide to inject case by case, according to the nature of the disease and the associated treatment and ensure a particular follow-up of these patients.

- There is no clinical data available concerning the tolerance of the *Juvéderm*[®] *VOLUMA*[®] XC injection in patients presenting a history of severe allergies or anaphylaxis. The practitioner should therefore decide to inject case by case, according to the nature of the disease and the associated treatment and ensure a particular follow-up of these patients.
- 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.
- *Juvéderm*[®] *VOLUMA*[®] XC should be used with caution in patients showing symptoms of cardiac conduction disorders.
- The combination of *Juvéderm*[®] *VOLUMA*[®] XC with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is inadvisable.
- Patients should be recommended not to apply make-up for 12 hours after the injection and to avoid prolonged exposure to sunlight, UV light, freezing temperatures or using saunas or Turkish baths for the two weeks after the injection.
- Do not inject more than 2mL per treatment site during each session.
- Patients are recommended to avoid massaging the implantation site and/or putting pressure on it for a few days following the injection.
- If the needle or cannula is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle or cannula.
- Athletes should be made aware that this product contains an active principle that may produce a positive result in anti-doping tests.
- The composition of this product is compatible with fields used for magnetic resonance imaging.
- Confirm the integrity of the sterility protector before use.
- Do not re-use.
- Do not re-sterilise.
- The needle and cannula used must be disposed of in a special receptacle.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. *Juvéderm*[®] *VOLUMA*[®] XC injectable gel should never therefore be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.

Adverse Effects

Practitioners must inform the patient that there are potential side effects associated with implantation of this device, which may occur immediately or may be delayed. These include (non-exhaustive list):

- Inflammatory reactions (e.g. redness, oedema, erythema) which may be associated with itching, pain on pressure, occurring after the injection. These reactions may last for a week.
- Haematomas
- Induration or nodules at the injection site.

- Discolouration of the injection site.
 - Poor effect or weak filling effect.
 - Cases of glabellar necrosis, abscess formation, granuloma and hypersensitivity have all been reported in the literature following hyaluronic acid injection. It is therefore important to take such possible complications into account.
 - Patients must report inflammatory reactions which persist for more than one week or any other secondary effect which develops, to their practitioner as soon as possible. The practitioner should treat these as appropriate.
- Any other undesirable side effects associated with injection of *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel must be reported to the distributor.

Pharmaceutical Precautions

Juvéderm[®] *VOLUMA*[®] *XC* injectable gel must be used prior to the expiration date printed on the package.

Juvéderm[®] *VOLUMA*[®] *XC* injectable gel has a shelf life of 24 months when stored between 2°C and 25°C.

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

Medicine Classification

Prescription Medicine

Package Quantities

Each box contains 1 syringe of *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel, 2 23G1" disposable sterile Ultra Thin Wall needles and 2 sterile 18G 70mm cannula reserved for injection of *Juvéderm*[®] *VOLUMA*[®] *XC* injectable gel.

A product leaflet and a set of labels showing the batch number, one of which should be attached to the patient's file and the other should be given to the patient in order to ensure traceability.

Name and Address

Allergan New Zealand Limited
Cnr Manu Tapu Drive & Joseph Hammond Place,
Auckland International Airport,
Mangere
Auckland 1
New Zealand

Date of Preparation

July 2010