Patient Information Leaflet
Juvéderm® VOLUX™
(hyaluronic acid injectable gel)

1. NAME AND MODEL

This product is Juvéderm® VOLUX™.

Each box of Juvéderm® VOLUX™ contains 2 syringes each filled with 1 mL hyaluronic acid injectable gel.

Product Description / What is Juvéderm® VOLUX™?

Juvéderm® VOLUX™ is a smooth, clear, colourless gel which contains hyaluronic acid to help retain natural moisture and softness in the skin and lidocaine (local anaesthetic) which helps improve comfort to the patient during injection.

2. INTENDED PURPOSE / INDICATION

What is the use of Juvéderm® VOLUX™?

Juvéderm® VOLUX™ is an injectable implant intended to restore and create volume of the face. The presence of lidocaine is meant to reduce the patient's pain during treatment.

Who can be injected with Juvéderm® VOLUX™?

Juvéderm® VOLUX™ is indicated for adults (over the age of 18).

3. CONTRAINDICATIONS, WARNING AND LIMITATIONS FOR USE

You should **not** use this product if:

- you suffer from untreated epilepsy
- you tend to develop scarring
- you are allergic to hyaluronic acid and/or to gram positive bacterial proteins as hyaluronic acid is produced by *Streptococcus* type of bacteria
- you are allergic to lidocaine or to similar local anaesthetics
- you are suffering from a rare genetic (inherited) disease that causes build-up of porphyrins which are the building blocks for haemoglobin
- you are suffering from skin inflammation
- you are suffering from a skin infection, such as acne, herpes, etc.
- you are pregnant or breastfeeding.

Your medical practitioner should not inject Juvéderm® VOLUX™ into blood vessels (intravascular injection).

Your medical practitioner should not inject Juvéderm® VOLUX™ in the eyelid, under-eye area, for crow's feet lines, for glabellar lines or in the lips.

4. SPECIAL OPERATING INSTRUCTIONS FOR USE/ PRECAUTIONS

How should Juvéderm® VOLUX™ be used?

This product is designed to be injected in the appropriate areas requiring treatment by an authorised health care professional who has had appropriate training and experience in injection techniques for volume restoration and creation.

Before treatment:

Tell your medical practitioner:

1) In case you are using the following medications:

- anti-coagulation medication (substances that can prolong bleeding), such as :
  - warfarin
  - acetylsalicylic acid
  - nonsteroidal anti-inflammatory drugs
  - other substances known to increase clotting time such as herbal supplements with garlic or ginkgo biloba, etc.
- medicines that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.). Their use is not recommended due to the presence of lidocaine.

2) If you have had any prior treatments with facial injectables.

3) In case you are suffering from any of the following medical conditions:

- History of, or currently suffering from, autoimmune disease or immune deficiency or immunosuppressive therapy. Your medical practitioner will 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 advise you if any specific monitoring will be required in your case. Patients with impaired immune systems may be at an increased risk for infection after injection of dermal fillers depending on their disease state. A determination of individual risks and benefits will be considered by the medical practitioner before deciding whether or not to proceed with the injection.

- History of streptococcal disease (such as recurrent sore throats, acute rheumatic fever, etc). Your medical practitioner may require you to have skin testing for hypersensitivity before any injection is administered. In the event of acute rheumatic fever with heart complications, it is the manufacturer's recommendation not to inject the product.

- Symptoms of heart disease.

- History of severe and/or multiple allergies. Your medical practitioner will then be able to decide on the indication on a case-by-case basis, according to the nature of the allergy and shall also ensure if you require any specific monitoring. In particular, a decision may be taken to propose skin testing for hypersensitivity or suitable preventive treatment for you prior to any injection. In case of history of anaphylactic shock, it is the manufacturer's recommendation not to inject the product.

You should not have this procedure at the same time as with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is the manufacturer's recommendation not to inject the product if the inflammatory reaction is significant.

This product is not intended to be injected into an area which has been previously treated with a permanent implant to limit risk of chronic/serious adverse events such as granuloma/areas of inflammation which have been reported with subsequent injections.

After treatment:

You should not use any makeup for at least 12 hours following the injection treatment and you should avoid extended exposure to the sun, ultraviolet (UV) rays and temperatures below 0°C, as well as any sauna or hammam sessions, during the two weeks following the injection treatment.

You should avoid massaging or putting pressure on the treated areas for a few days following the injection.

5. INTENDED PERFORMANCE

Juvéderm® VOLUX™ is an injectable implant intended to restore and create volume of the face. The presence of lidocaine is meant to reduce the patient’s pain during treatment.

6. UNDESIRABLE SIDE EFFECTS

What are the possible side effects?

The most common side effects include temporary reactions at the treatment site which are consistent with other facial-injection procedures.

Potential side effects are associated with implantation of this product, which may occur immediately or may be delayed. These include but are not limited to:

- Inflammatory reactions (redness, swelling, etc.), which may be associated with itching and/or pain on pressure and/or abnormal skin sensation, occurring after the injection. These reactions may last for a week.

- Bruising (haematomas)

- Hardened mass at the injection site

- Staining or discolouration of the injection site might be observed, especially when hyaluronic acid dermal filler is injected too superficially and/or in thin skin (Tyndall effect)

- Poor effect or weak 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, slowing down of blood supply to the brain (cerebral ischaemia) or bleeding in that area leading to stroke (cerebral haemorrhage), skin tissue cell-death (necrosis) and damage to underlying tissues/structures

- Pus formation, area of inflammation and immediate or delayed allergic reactions after hyaluronic acid and/or lidocaine injections have also been reported.

Please see section 9*: SYMPTOMS OR SIGNS OF DEVICE OR TREATMENT MALFUNCTION* for further information.

If you believe that you have experienced an undesirable effect related to Juvéderm® VOLUX™ injectable gel, you should call your medical practitioner and/or the local sponsor of the product, AbbVie Pty Ltd, please see section 13: *ADDITIONAL INFORMATION / CONTACT.*

7. RISKS & ASSOCIATED PRECAUTIONS

What are residual risks?

Residual risks could arise due to any shortcoming of the protection measures adopted as part of the medical device guideline. Please refer to information provided in section 12: *RESIDUAL MATERIAL*.

What are risks that could arise from interaction of Juvéderm® VOLUX™ with other equipment or material?

Juvéderm® VOLUX™ does not interact with other medical and/or electrical equipment and is compatible with fields used for magnetic resonance imaging.

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride.

Juvéderm® VOLUX™ contains lidocaine, there is no known interaction with other local anaesthetics.

Because of the risks associated with treatment with Juvéderm® VOLUX™, the following precautions and other measures, should be taken:

By Health care professionals/Medical practitioners:
Juvéderm® VOLUX™ should never be placed in contact with quaternary ammonium salts such as benzalkonium chloride or with medical-surgical instrumentation which has been treated with this type of substance.

By the patient:
Please refer to Section 4: *SPECIAL OPERATING INSTRUCTIONS FOR USE/ PRECAUTIONS* for further information with regards to precautions to be followed before and after treatment with Juvéderm® VOLUX™.

8. FOLLOW-UP CONSULTATION

What is the nature and frequency of regular follow-up, examination, monitoring or maintenance following treatment that you need to undertake?
It is suggested to have a follow-up consultation with your healthcare professional approximately 2 weeks after the procedure. This is an opportunity to discuss any potential adverse effects you have observed.

A touch up treatment (for achieving optimal correction) with Juvéderm® VOLUX™ might be required which can also be completed at this follow-up consultation.

9. SYMPTOMS OR SIGNS OF DEVICE OR TREATMENT MALFUNCTION

What are the symptoms or signs that could indicate the device is malfunctioning or treatment is not as expected?
Your medical practitioner will stop the procedure if any of the following symptoms are seen during the injection: changes in vision, signs of stroke, whitening/paling of the skin or unusual pain during or shortly after the procedure.

There are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. Please see section 6: *UNDESIRABLE* SIDE EFFECTS for further information.

What precautions and other measures should you take if the performance of the device changes or if you experience any undesirable side effects?
Before treatment:
Your medical practitioner should have discussed with you the product's indications, contra-indications, incompatibilities and potential undesirable effects/risks associated with dermal filler injection and ensure that you are aware of the signs and symptoms of potential complications.

After treatment:
Please report the following to your medical practitioner as soon as possible for appropriate treatment:

- inflammatory reactions for more than one week or
- any other side effect that has developed

If you believe that you have experienced an undesirable effect related to Juvéderm® VOLUX™ injectable gel, you should call your medical practitioner and/or the local sponsor of the product, AbbVie Pty Ltd please see section 13: *ADDITIONAL INFORMATION / CONTACT*.

10. DEVICE LIFETIME/DURATION OF TREATMENT EFFECT

What is the life time of the product? Does the treatment last forever?

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. It will also vary with the individual patient being treated.

What could shorten or lengthen the treatment lifetime?

Please refer to information provided in paragraph above.

What precautions and other measures you should take at, or near, the end of the expected device lifetime?

For maintaining optimal correction, a repeat treatment with Juvéderm® VOLUX™ might be required. You can contact your medical practitioner for further information.

Under what circumstances should you contact a health professional in relation to the operation/use of Juvéderm® VOLUX™?

Please refer to information provided in section 9: *SYMPTOMS OR SIGNS OF DEVICE OR TREATMENT MALFUNCTION*.

11. COMPOSITION

What material & substances are included in Juvéderm® VOLUX™?

Each 1 mL syringe contains:

- Hyaluronic acid gel: 25 mg
- Lidocaine (lignocaine) hydrochloride monohydrate: 3 mg
- Phosphate buffer pH 7.2 to make 1 mL

12. RESIDUAL MATERIAL

What are the manufacturing residuals that could pose a risk to you?

This product does not contain any manufacturing residuals that can pose a risk to patients.

13. ADDITIONAL INFORMATION / CONTACT

What to do in case of any serious incident that occurs in relation to Juvéderm® VOLUX™?

Any serious incident with Juvéderm® VOLUX™ should be reported to the manufacturer and to the Therapeutic Goods Administration. If you believe you have experienced an incident/side effect after treatment with Juvéderm® VOLUX™ injectable gel, you should contact Allergan Aesthetics by email to MedDeviceComplaintsAPAC@AbbVie.com or call 1800 252 224 and contact the Therapeutic Goods Administration at https://www.tga.gov.au/.

ALLERGAN

Allergan Aesthetics

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