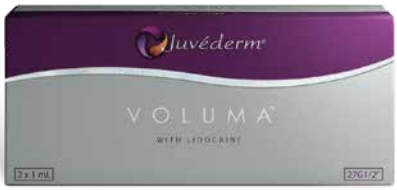
THE VYCROSS® COLLECTION

Juvéderm® VOLBELLA®
with lidocaine

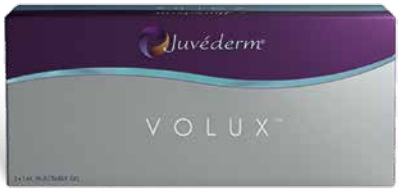
Juvéderm® VOLIFT®
with lidocaine



Juvéderm® VOLUMA®
with lidocaine

Juvéderm® VOLIFT® Retouch®
with lidocaine

Juvéderm® VOLITE™
with lidocaine



Juvéderm® VOLUX™
with lidocaine

TREATMENT RECORD

Consent and consultation form for patients treated with products from the VYCROSS® Collection: (Juvéderm® VOLUMA® with lidocaine, Juvéderm® VOLIFT® with lidocaine, Juvéderm® VOLIFT® Retouch® with lidocaine, Juvéderm® VOLBELLA® with lidocaine, Juvéderm® VOLITE™ with lidocaine), Juvéderm® VOLUX™ with lidocaine

Patient name: ..... Date of birth: .....

Address: .....

.....

.....

Contact numbers: .....

Email: .....

MEDICAL HISTORY

Please complete the following medical questionnaire

Are you pregnant or breast feeding? Y N

Do you have a history of severe allergy/anaphylaxis? Y N

Are you currently receiving any medical treatment? Y N

If yes, please provide more details: .....

.....

Have you previously received any aesthetic treatments (e.g. laser, peels, dermabrasion etc.)

If yes, please provide more details: .....

.....

Have you had any treatment with absorbable dermal fillers, semi-permanent/permanent dermal fillers or botulinum toxin? Y N

If yes, which treatment did you receive, what areas were treated and when? .....

.....

.....

Did you experience any side effects related to the treatment? If yes, please provide details: .....

.....

.....

Have you ever suffered from auto-immune disease or disease affecting the immune system? Y N

Do you have any cutaneous (skin) infection or inflammatory problems (e.g. herpes, acne etc.)? Y N

Are you currently taking any steroids, aspirin, anticoagulant (e.g. warfarin etc.) or certain drugs that reduce or inhibit the hepatic metabolism? Y N

Do you suffer from acute rheumatic fever or recurrent sore throat? Y N

Do you suffer from any allergies, in particular allergies to hyaluronic acid, amide type local anaesthetics or lidocaine? Y N

Do you suffer from untreated epilepsy? Y N

Do you tend to develop hypertrophic scarring? Y N

Do you suffer from porphyria? Y N

Do you suffer from cardiac conduction disorders? Y N

If yes, please provide details: .....

.....

If the answer is yes to any of the above, your medical practitioner may ask for further details. Treatment may be refused if it is not considered in your own interest to proceed.

ADVISED CONSENT

I confirm I have been informed that:

The products in the VYCROSS® Collection (Juvéderm® VOLUMA® with lidocaine, Juvéderm® VOLIFT® with lidocaine, Juvéderm® VOLIFT® Retouch® with lidocaine, Juvéderm® VOLBELLA® with lidocaine, Juvéderm® VOLITE™ with lidocaine , Juvéderm® VOLUX™ with lidocaine), are a non-animal, hyaluronic acid-based (sugar-based), non-permanent transparent gel which is injected to:

- Restore facial volume (Juvéderm® VOLUMA® with lidocaine)
- Treat deep skin depressions, face contouring and volume restoration (Juvéderm® VOLIFT® with lidocaine, Juvéderm® VOLIFT® Retouch® with lidocaine)
- Treat fine lines and medium-sized skin depressions as well as enhancement and pouting of the lips (Juvéderm® VOLBELLA® with lidocaine)
- Treat fine lines and for additional improvement of skin quality attributes such as hydration and elasticity (Juvéderm® VOLITE™ with lidocaine)
- Restore and create volume of the lower face (Juvéderm® VOLUX™ with lidocaine)

Treatment with Juvéderm® VOLUMA® with lidocaine may remain effective for up to 24 months[1,2]; treatment with Juvéderm® VOLUX™ with lidocaine for up 18-24 months[3,4*]; treatment with Juvéderm® VOLIFT® and VOLIFT RETOUCH® with lidocaine for up 18 months[5,6†]; treatment with Juvéderm® VOLBELLA® with lidocaine for up to 12 months[7,8‡] and treatment with Juvéderm® VOLITE™ with lidocaine is proven to improve dermal hydration for up to 9 months[9§]. This will vary depending on the skin type, areas treated, quantity of product injected, the injection technique and lifestyle factors such as sun exposure and smoking.

A touch up session may be recommended a few weeks after the first session to increase the effects and maximise the results. You should be made aware that the products contain 0.3% lidocaine (HCl) which may produce a positive result in anti-doping tests.

After an injection with either one, two, three, four, five or six of the VYCROSS® Collection* products, inflammatory skin reactions (for example, redness, swelling, rash), which may be accompanied by itchiness or pain on application of pressure, may occur. These reactions may last up to a week. Bruising, lumps or nodules may appear at the injection site. Very rarely, cases of discolouration or lightening at the injection area have been reported. Rare cases of necrosis (cell death), abscesses (collection of pus), granulomas (foreign body reaction) and immediate or delayed hypersensitivity (allergic reactions) have also been reported after hyaluronic acid injections and/or lidocaine, as have poor or weak filling effects.

After treatment, please avoid extreme facial expressions, alcohol consumption and applying make up for 12 hours. Please avoid extreme sun exposure, UV light, temperatures below 0°C, saunas and steam rooms for 2 weeks after treatment. It is advisable to avoid strenuous activity or exercise for up to 24 hours and to avoid massaging the treated area. Try to sleep with the head elevated and avoid sleeping on the injected areas for one or two days.

The use, indications, contraindications (specific situations in which the six VYCROSS® Collection products: Juvéderm® VOLUMA® with lidocaine, Juvéderm® VOLIFT® with lidocaine, Juvéderm® VOLIFT® Retouch® with lidocaine, Juvéderm® VOLBELLA® with lidocaine, Juvéderm® VOLITE™ with lidocaine, Juvéderm® VOLUX™ with lidocaine, should not be used) and the possible side effects have been explained to me. There are specific situations in which one, two, three, four, five or six VYCROSS® Collection* products should not be used, these can be identified from my medical history. I have accurately and truthfully answered all the questions regarding my previous medical and aesthetic treatment history to the best of my knowledge. I was given the opportunity to ask questions and I am satisfied with the answers given.

If inflammatory reactions persist for more than one week, or if any other side effects appear, I will inform my medical practitioner who will treat appropriately. Whilst rare, such side effects may require treatment lasting several months before they disappear.

On a voluntarily undertaken basis:

I am interested in speaking to the media about my experience with products from the VYCROSS® Collection* and my medical practitioner can provide more information about this. (Please tick appropriate box)

I agree I disagree

My medical practitioner may use pictures taken before and after my treatment for the following purposes.
I have seen these pictures and agree or disagree with their use as follows (Please tick the appropriate boxes):

Scientific purposes I agree I disagree

Media purposes I agree I disagree

I have read and understood the post-injection recommendations and undertake to observe them.

* The VYCROSS® Collection = either one, two, three, four, five or six of the following products: Juvéderm® VOLUMA® with lidocaine, Juvéderm® VOLIFT® with lidocaine, Juvéderm® VOLIFT® Retouch® with lidocaine, Juvéderm® VOLBELLA® with lidocaine, Juvéderm® VOLITE™ with lidocaine , Juvéderm® VOLUX™ with lidocaine.

Name: ..... Signed: ..... Date: .....

Lot number: .....

Date: .....

Notes: .....

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Lot number: .....

Date: .....

Notes: .....

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Health Care Professional's Name: .....

Clinic Name: .....

Clinic Address: .....

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Telephone: .....

Email: .....

* Based on comparative preclinical in vitro testing and results from repeat treatment data, added to Juvéderm® VOLUX clinical study showing duration beyond 18 months after initial treatment or initial + top-up treatment in the chin and jaw, as well as clinical results for predicate device Juvéderm® VOLUMA with lidocaine showing 24 month duration in the mid-face established Juvéderm® VOLUX as having an in situ duration of 18–24 months.[4]

† 18-month duration in NLFs from clinical data. Within 4 weeks after the Month 9, 12, or 15 visits, patients could request a single, unilateral treatment to correct clinically significant asymmetry (at least 1-point difference in NLF severity between NLFs, based on the Evaluating Investigator assessment).[5]

‡ Study conducted using Juvéderm® VOLBELLA without lidocaine.[7] The addition of lidocaine does not alter the physical properties of Juvéderm® products.[10]

§ Cheek skin hydration, as measured by the MoistureMeter® D instrument, significantly improved from baseline at Months 1, 4, 6 and 9.[10]

References:

1. Callan P *et al. Clin Cosmet Investig Dermatol.* 2013;6:81–89. **2.** Jones D and Murphy DK. *Dermatol Surg.* 2013;39:1602–12. **3.** Allergan. Data on File. INT/0654/2018. Juvéderm® VOLUX final clinical study report & clinical evaluation report – efficacy and duration data. Oct 2018. **4.** Allergan. Data on File. INT/0074/2019. Juvéderm® VOLUX final clinical evaluation report. Jan 2019. **5.** Allergan. Data on File. INT/0214/2017. Juvéderm® VOLIFT XC US clinical study results (V17-001). Mar 2017. **6.** Allergan. Data on File. INT/0607/2017. Juvéderm® VOLIFT NLFSS responder rates (S17L-001). Aug 2017. **7.** Eccleston D and Murphy DK. *Clin Cosmet Investig Dermatol.* 2012;5:167–72. **8.** Niforos F *et al. Dermatol Surg.* 2017;43(10):1271–80. **9.** Niforos F *et al.* Poster Presentation at Beauty Through Science (BTS) Congress, Stockholm, Sweden; 2017. **10.** Raspaldo H *et al. J Cosmet Dermatol.* 2010;9:11–15.