Before beginning your treatments, please review this important information.

1. GLOSSARY
(Note that terms in the glossary are bold throughout this document.)

- Anesthetic — a substance that reduces sensitivity to pain
- Asymmetry correction — an additional treatment with dermal filler that is given to balance the effect after the initial treatment has worn off on one side of the face
- Hyaluronic acid (HA) — a polysaccharide (sugar) that is naturally in the body. It keeps skin moisturized and soft. HA fillers, including the JUVÉDERM® range of products, are a modified form of the HA that is naturally in your body
- Lidocaine — a synthetic compound used as a local anesthetic to decrease pain
- Nasolabial folds (NLFs) — the lines or wrinkles that run from the corners of the nose downward toward the corners of the mouth
- Pigmentation disorders — a medical condition that results in a change in skin color
- Repeat injection — an additional treatment with dermal filler that is given after the effects of the initial treatment have worn off, in order to maintain the desired result
- Touch-up — an additional injection of a small amount of dermal filler usually given about 2 weeks to 1 month after the initial injection. A touch-up treatment may be necessary to achieve the desired result
- VYCROSS® technology — a unique manufacturing process that provides a high concentration of crosslinked HA for long-lasting results. It creates a smooth-consistency gel that flows easily into the skin

2. PRODUCT DESCRIPTION
What is it?
JUVÉDERM® VOLLURE™ XC injectable gel is a smooth, clear, colorless hyaluronic acid (HA) gel that contains a small quantity of local anesthetic (lidocaine). HA is a naturally occurring sugar found in the human body. The role of HA in the skin is to help retain natural moisture and softness. The lidocaine helps to improve the comfort of the injection.

JUVÉDERM® VOLLURE™ XC injectable gel is manufactured using VYCROSS® technology to give a specialized smooth-gel filler that produces long-lasting results for up to 18 months at the treatment site.

What is it for?
JUVÉDERM® VOLLURE™ XC is injected with an ultrafine needle into areas of facial tissue where moderate to severe facial wrinkles and folds (such as nasolabial folds) occur.

How does it work?
As you age, wrinkles develop on your face, and nasolabial folds may become more visible. JUVÉDERM® VOLLURE™ XC is designed to temporarily reverse signs of aging by adding subtle volume to facial wrinkles and folds (such as nasolabial folds) and restoring a smoother appearance to the face in patients over the age of 21. The lidocaine in the gel improves the comfort of the injection by reducing sensitivity to pain.

3. CONTRAINDICATIONS
Are there any reasons why I should not receive JUVÉDERM® VOLLURE™ XC injectable gel?
Your doctor will ask about your medical history to determine if JUVÉDERM® VOLLURE™ XC is right for you. You should not use JUVÉDERM® VOLLURE™ XC if:
- You have severe allergies with a history of severe reactions (anaphylaxis) or history or presence of multiple severe allergies. Use may result in an allergic reaction.
- You are allergic to lidocaine or to the proteins used to make the HA in JUVÉDERM® VOLLURE™ XC (Gram-positive bacterial proteins). Use may result in an allergic reaction.

If you are not sure about your medical history concerning these allergies, please discuss further with your doctor.

4. PRECAUTIONS
What precautions should my doctor advise me about?
The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications:
- Avoid strenuous exercise, exposure to extensive sun or heat, and consumption of alcoholic beverages within the first 24 hours following treatment. These may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are using any medication that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may increase bruising or bleeding at the injection site.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of JUVÉDERM® VOLLURE™ XC injectable gel in patients with a history of excessive scarring has not been studied and may result in additional scars.
- Tell your doctor if you have a history of pigmentation disorders. The safety of JUVÉDERM® VOLLURE™ XC in patients with a history of pigmentation disorders has not been studied. Use in these patients may result in changes in pigmentation.

5. CLINICAL STUDY
How was the product studied?
To establish the safety and effectiveness of JUVÉDERM® VOLLURE™ XC for smoothing the appearance of facial wrinkles and folds, 123 subjects were treated with JUVÉDERM® VOLLURE™ XC in 1 NLF and another dermal filler (control) in the opposite NLF. To achieve subjects’ desired results, an optional touch-up treatment was allowed 1 month after initial treatment, and 24 subjects elected to receive asymmetry correction at 9, 12, or 15 months. Between 12 to 18 months 84 subjects elected to receive a repeat treatment.

The amount of JUVÉDERM® VOLLURE™ XC used in the clinical study to achieve optimal outcomes ranged from 0.1 mL to 3.0 mL per NLF, with a median volume of 1.7 mL. To maintain the desired results, approximately one-third of the amount (0.6 mL) per NLF was needed for the repeat injection.

To evaluate the safety of JUVÉDERM® VOLLURE™ XC, subjects noted common side effects in daily diaries. Side effects were also reported by doctors during office visits with each subject. These office visits included discussing any symptoms or complaints with the subjects and assessing the appearance of the subjects’ NLFs. To evaluate the effectiveness of the product, a 5-point Wrinkle Assessment Scale was used.

6. BENEFITS
What will it accomplish?
The results of the JUVÉDERM® VOLLURE™ XC clinical study showed that the product will temporarily smooth and reduce the appearance of moderate to severe facial wrinkles and folds such as nasolabial folds.

What did the clinical study show?
JUVÉDERM® VOLLURE™ XC was found to effectively smooth and reduce the appearance of moderate to severe facial wrinkles and folds. The clinical study showed that JUVÉDERM® VOLLURE™ XC lasted through 18 months in the majority (89%) of subjects.

The study doctors reported that:
- 93% of subjects had a 1-point-or-greater improvement in NLF severity 6 months after treatment
- 59% of subjects had a 1-point-or-greater improvement in NLF severity 18 months after treatment

Subjects reported:
- Approximately 82% of the subjects were highly satisfied with their treatment results 6 months after the injection
- Approximately 68% of the subjects were highly satisfied with their treatment results 18 months after the injection
- Improvement in the appearance of their NLFs based on how bothered they were with the depth of their NLF, the look of their NLF when relaxed and smiling, how old their NLF makes them look, and how their NLF looks compared with other people their age
- 96% of subjects improved in the appearance of their NLFs at 6 months
- 62% of subjects improved in the appearance of their NLFs at 18 months

(Continued on reverse side.)
What side effects were seen in the clinical study?

Subjects reported side effects in 30-day daily diaries. If these side effects lasted longer than 30 days, they were reported as adverse events. Adverse events could also be reported by doctors at any time throughout the study.

Based on the clinical study, the likelihood of experiencing side effects after treatment with JUVÉDERM® VOLLURE™ XC is shown below in Table 1. A majority of subjects (95%) in the clinical study experienced a side effect, such as firmness, swelling, tenderness to touch, lumps/bumps, redness, pain, bruising, itching, and discoloration at the injection site, as reported in their 30-day daily diaries. These side effects were usually mild (easily tolerated) or moderate (uncomfortable) in severity, although some subjects experienced severe side effects (incapacitating). The majority of the side effects went away on their own within 1 week. Some side effects lasted longer than 1 week. The most common side effects that lasted longer than 1 week were firmness (43%) and lumps/bumps (36%).

Table 1. Side Effects After Treatment

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Likelihood of Experiencing Side Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Side Effect</td>
<td>95 out of 100 people (95%)</td>
</tr>
<tr>
<td>Firmness</td>
<td>89 out of 100 people (89%)</td>
</tr>
<tr>
<td>Swelling</td>
<td>86 out of 100 people (86%)</td>
</tr>
<tr>
<td>Tenderness to Touch</td>
<td>84 out of 100 people (84%)</td>
</tr>
<tr>
<td>Lumps/Bumps</td>
<td>82 out of 100 people (82%)</td>
</tr>
<tr>
<td>Redness</td>
<td>74 out of 100 people (74%)</td>
</tr>
<tr>
<td>Pain</td>
<td>72 out of 100 people (72%)</td>
</tr>
<tr>
<td>Bruising</td>
<td>57 out of 100 people (57%)</td>
</tr>
<tr>
<td>Itching</td>
<td>31 out of 100 people (31%)</td>
</tr>
<tr>
<td>Discoloration</td>
<td>27 out of 100 people (27%)</td>
</tr>
</tbody>
</table>

*Occurring in > 5% of subjects.

*Based on 122 subjects who provided information about side effects after their initial treatment.

What adverse events were seen in the clinical study?

Adverse events (any side effects that lasted longer than the 30-day daily diary, or adverse events reported by doctors at any time throughout the study) were reported over the course of the study. After treatment with JUVÉDERM® VOLLURE™ XC, most of the adverse events were rated as mild or moderate. The most common adverse events for subjects were the same as those reported in the daily diary, such as firmness, lumps/bumps, and swelling. Severe adverse events included firmness, lumps/bumps, swelling, itching, redness, and bruising. Most of these adverse events went away on their own without any long-term effects. One subject had mild swelling that did not go away by the end of the study.

Subjects experienced similar adverse events after repeat injection.

In the clinical study, 3 adverse events occurred weeks to months after the injection procedure. These events included mild swelling, moderate skin mass, and severe itching. The swelling was treated with anti-inflammatory medicines, the skin mass was treated with topical corticosteroid cream, and the itching did not require any treatment. All 3 events went away without any long-term effects.

What are other possible adverse events?

As with all skin-injection procedures, there is a risk of infection.

One of the risks with using this product is the unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

Although most side effects will go away with time, your doctor may choose to treat them with medications, such as antibiotics, steroids, or hyaluronidase (an enzyme that breaks down HA).

What should I do if I have additional questions?

For further questions and information, please call Allergan at 1-800-766-0171.

Allergan Product Surveillance line during normal business hours at 1-877-345-5372

To report any side effects.

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