1. DEVICE DESCRIPTION

JUVÉDERM® Ultra XC is a sterile, biodegradable, non-pyrogenic, viscous, clear, colorless, homogeneous gel implant. It consists of cross-linked hyaluronic acid (HA) produced by Streptococcus species of bacteria, formulated to a concentration of 24 mg/mL and 0.3% w/w lidocaine in a physiologic buffer.

2. INTENDED USE/INDICATIONS

- JUVÉDERM® Ultra XC injectable gel is indicated for injection into the mid to deep dermis for correction of moderate to severe facial wrinkles and folds (such as nasolabial folds).
- JUVÉDERM® Ultra XC is for injection into the lips and perioral area for lip augmentation in adults over the age of 21.

3. CONTRAINDICATIONS

- JUVÉDERM® Ultra XC is contraindicated for patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- JUVÉDERM® Ultra XC contains trace amounts of Gram-positive bacterial proteins and is contraindicated for patients with a history of allergies to such material.
- JUVÉDERM® Ultra XC contains lidocaine and is contraindicated for patients with a history of allergies to such material.

4. WARNINGS

- The product must not be injected into blood vessels. Introduction of JUVÉDERM® Ultra XC into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction. Take extra care when injecting soft-tissue fillers; for example, after insertion of the needle, and just before injection, the plunger rod can be withdrawn slightly to aspirate and verify the needle is not intravascular, inject the product slowly and apply the least amount of pressure necessary. Rare, but serious, adverse events associated with the intravascular injection of soft-tissue fillers in the face have been reported and include temporary or permanent vision impairment, blindness, cerebral ischemia or cerebral hemorrhage leading to stroke, skin necrosis, and damage to underlying facial structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in vision, signs of a stroke, blanching of the skin, or unusual pain during or shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate health care professional specialist should an intravascular injection occur (see Health Care Professional Instructions #13).
- Product use at specific sites in which an active inflammatory process (skin eruptions such as cysts, pimples, rashes, or hives) or infection is present should be deferred until the underlying process has been controlled.
- Injection site reactions consist mainly of short-term inflammatory symptoms starting early after treatment and lasting ≤ 7 days in facial wrinkles and folds, and typically last ≤ 14 days in the lips. Refer to the ADVERSE EVENTS section for details.

5. PRECAUTIONS

- JUVÉDERM® Ultra XC is packaged for single-patient use. Do not resterilize. Do not use if package is opened or damaged.
- In order to minimize the risks of potential complications, this product should only be used by health care professionals who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
- Health care professionals are encouraged to discuss all potential risks of soft-tissue injection with their patients prior to treatment and ensure that patients are aware of signs and symptoms of potential complications.
- Based on preclinical studies, patients should be limited to 20 mL of any JUVÉDERM® injectable gel per 60 kg (130 lbs) body mass per year. The safety of injecting greater amounts has not been established.
- The safety and effectiveness for the treatment of anatomic regions other than facial wrinkles and folds, lips, and perioral area have not been established in controlled clinical studies.
- As with all transcutaneous procedures, dermal filler implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
- JUVÉDERM® Ultra XC is to be used as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, homogeneity, and performance of the product and it can therefore no longer be assured.
- The safety for use during pregnancy, in breastfeeding females, or in patients under 18 years has not been established.
- The safety in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied.
- JUVÉDERM® Ultra XC should be used with caution in patients on immunosuppressive therapy.
- Patients who are using substances that can prolong bleeding (such as aspirin, nonsteroidal anti-inflammatory drugs, and warfarin) may, as with any injection, experience increased bruising or bleeding at injection sites.
- After use, treatment syringes and needles may be potential biohazards. Handle and dispose of these items in accordance with accepted medical practice and applicable local, state, and federal requirements.
- JUVÉDERM® Ultra XC injectable gel is a clear, colorless gel without visible particulates. In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe; notify Allergan® Product Support at 1-877-345-5372.
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with JUVÉDERM® Ultra XC, there is a possible risk of eliciting an inflammatory reaction at the implant site. An inflammatory reaction is also possible if the product is administered before the skin has healed completely after such a procedure.
- Failure to comply with the needle attachment instructions could result in needle disengagement and/or product leakage at the LUER-LOK® and needle hub connection.

6. ADVERSE EVENTS

A. Clinical Evaluation of JUVÉDERM® Ultra XC in the Nasolabial Folds (NLFs)

A 2-week, randomized, controlled U.S. clinical study for JUVÉDERM® Ultra XC compared with JUVÉDERM® Ultra without lidocaine showed a similar safety profile in all subjects (N = 36), with the exception of fewer reports of pain/tenderness with the product containing lidocaine. Common treatment site reactions by severity and duration, are presented in Tables 1 and 2. Aside from injection site responses, there were no adverse events related to the device, procedure, or anesthesia.

- The most common injection site responses for JUVÉDERM® Ultra XC were redness, swelling, tenderness, firmness, lumps/bumps, discoloration, and bruising.
B. Clinical Evaluation of JUVÉDERM® Ultra (Without Lidocaine) in the NLFs

In the initial randomized, controlled clinical trial to evaluate safety and effectiveness, 146 subjects were injected with JUVÉDERM® Ultra in one NLF and ZYPLAST® dermal filler in the contralateral NLF. Preprinted diary forms were used to subject to record specific signs and symptoms experienced during each of the first 14 days (day 0 through day 13) after initial and touch-up treatments. Subjects were instructed to rate each treatment response on the diary as “Mild,” “Moderate,” “Severe,” or “None.” None of the subjects participating in the study experienced any treatment-related adverse reactions. No treatment-related adverse reactions were reported after repeat treatment.

C. Clinical Evaluation of JUVÉDERM® Ultra XC for Lip Augmentation

In a randomized, controlled clinical trial to evaluate the safety and effectiveness of JUVÉDERM® Ultra XC for lip augmentation, 213 subjects were randomized to treatment and received injections in the lips and perioral area (N = 157), or to delayed-treatment control, and had treatment delayed 3 months (N = 56).

Preprinted diary forms were used to record specific signs and symptoms of ISRs experienced during the 30 days (Day 1 through Day 30) following initial treatment, touch-up treatment (if performed), and repeat treatment. Subjects were instructed to rate each symptom listed on the diary as Mild, Moderate, Severe, None, or More severe.

Mild ISRs were defined as causing some discomfort and having some effect on daily activities.

Moderate ISRs were defined as causing great discomfort and having significant effect on daily activities.

Severe ISRs were defined as causing complete inability to perform activities. ISRs reported by > 5% of the 193 subjects who completed post-treatment diary forms after initial treatment are summarized in Table 5.

The most common ISRs of JUVÉDERM® Ultra XC were pain and swelling. The incidence of pain in swelling and redness-related injection site responses was 70% (22/31). ISRs reported after initial treatment were more frequent and severe than ISRs reported after repeat treatment, with a frequency of 5 events or more and were not observed in the clinical study; this includes reports received globally from all sources including scientific journals and voluntary reports. All adverse events obtained through postmarket surveillance are listed in order of number of reports received: hematoma, inflammatory reaction, lack or loss of correction, unsatisfactory result, vascular occlusion, skin rash, overcorrection, bleeding at the injection site, allergic reaction, infections, pain or discomfort, injection site hypersensitivity, pigmentation, calcification, vision loss, traumatic injury, and granuloma.

In many cases, the symptoms resolved without any treatment. Repeat treatments include antibiotics, steroids, topical creams, hyaluronidase, anti-inflammatories, anti-histamines, needle aspiration and drainage, use of non-steroidal anti-inflammatory drugs anti-discomfort medications, and local anesthetic.

Vascular occlusion of vessels resulting in necrosis and vision abnormalities have been reported following injection of JUVÉDERM® products, with and without lidocaine, with a time to onset ranging from immediately to within one week after injection. These reports occurred in ≤ 0.5% of treated subjects, with no deaths or life-threatening events that would compromise performance of daily activities.

D. Other Safety Data

Other Clinical Studies

In addition to the randomized US clinical studies of other JUVÉDERM® formulations (without lidocaine) in a total of 293 subjects, the safety profile was similar to that described above for JUVÉDERM® Ultra. Postmarket Surveillance

The following adverse events were received from postmarket surveillance for JUVÉDERM® Ultra and Ultra Plus, with and without lidocaine, with a frequency of ≥ 5% and ≥ 15% for more and were not observed in the clinical study; this includes reports received globally from all sources including scientific journals and voluntary reports. All adverse events obtained through postmarket surveillance are listed in order of number of reports received: hematoma, inflammatory reaction, lack or loss of correction, unsatisfactory result, vascular occlusion, skin rash, overcorrection, bleeding at the injection site, allergic reaction, infections, pain or discomfort, injection site hypersensitivity, pigmentation, calcification, vision loss, traumatic injury, and granuloma.

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**Study Endpoints**

The primary effectiveness endpoint for the study was the IER's NLF severity score over the post-treatment follow-up period. Effectiveness of device treatment was demonstrated by a lowering of the IER NLF severity score. Additional analyses assessed the subject and the Investigator’s live NLF severity assessments.

**Subject Demographics**

A total of 140 subjects ranging in age from 25 to 75 years were randomized and treated, and 140 (96%) completed the 6-month follow-up period. Prior to enrollment, 87% (60%) had previous experience with other facial dermal treatments (eg, alpha-hydroxy agents, neurotoxin, microdermabrasion, or retinoid acid).

**Subject demographics and pretreatment characteristics of the JUVÉDERM® Ultra effectiveness population are presented in Table 6.**

<table>
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<tr>
<th>Table 6. Demographics and Pretreatment Characteristics of the Effectiveness Population (Number/% of Subjects)</th>
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<tr>
<td>N = 146</td>
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<td><strong>Gender (Number/%)</strong></td>
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<td><strong>Race (Number/%)</strong></td>
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<td><strong>Ethnicity (Number/%)</strong></td>
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<td><strong>Mean Baseline NLF Severity Score</strong></td>
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<td><strong>Fitzpatrick Skin Type</strong></td>
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<td><strong>Mean Baseline NLF Severity Score</strong></td>
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**Effectiveness Results**

The primary effectiveness results for JUVÉDERM® Ultra based on the IER's assessment of NLF severity are presented in Table 7.

<table>
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<tr>
<th>Table 7. Effectiveness Summary: Independent Expert Reviewer’s NLF Severity Scores (Number/% of Subjects)</th>
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<tr>
<td>N = 146</td>
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<tr>
<td><strong>NLF (N) = 146 NLFs)</strong></td>
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<tr>
<td><strong>Baseline</strong></td>
</tr>
<tr>
<td><strong>18 weeks</strong></td>
</tr>
<tr>
<td><strong>52 weeks</strong></td>
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<tr>
<td><strong>Follow-up Weeks &gt; 36</strong></td>
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</table>

All subjects returning for repeat treatment were stratified into 2 groups based on the time elapsed between last initial treatment and repeat treatment: 25 to 36 weeks or >36 weeks. Improvement since baseline was clinically significant (≥1 point) for both groups, with a large majority of subjects treated with JUVÉDERM® Ultra demonstrating improvement:

- 75% (36/48) beyond 36 weeks (months 6-9 months)
- 87% (20/23) at 24 weeks and 78% (7/9) at 48 weeks (1 year)

A total of 36 subjects received a single treatment with JUVÉDERM® Ultra XC in NLFs and had treatment delayed approximately 3 months. The NLFs were significantly lower (p < 0.001) than the IER NLF severity score in the other NLF. Within 30 minutes after both NLFs were treated, the subjects rated procedural pain on an 11-point scale and a 5-point comparative scale. Both the Investigators and subjects rated NLF severity at baseline and 2 weeks after treatment using the 5-point NLF severity scale. The investigator, subject, and patient used an interactive voice-response-system diary to record common treatment site reactions for 14 days.

**C. Clinical Study for JUVÉDERM® Ultra XC for Treatment of NLFs**

A prospective, double-blind, randomized, within-subject, controlled, multicenter clinical study was conducted to evaluate the safety and effectiveness of JUVÉDERM® Ultra XC compared with JUVÉDERM® Ultra without lidocaine. The purpose of this study was to evaluate the level of procedural pain (pain during injection) experienced by subjects when treated with each product. The duration of the study was 2 weeks.

A total of 36 subjects were randomized to either treatment with JUVÉDERM® Ultra XC (N = 157) or to delayed-treatment control (N = 56), and had treatment delayed approximately 3 months. Treatment group subjects underwent treatment with JUVÉDERM® Ultra XC at the outset of the study, followed by an optional touch-up treatment 2-4 weeks after the initial treatment, if deemed necessary by the subject or the clinician's clinical judgment. The primary follow-up period consisted of office visits at 1 and 3 months after the last treatment. Control subjects also completed 1 and 3 month follow-up visits. Thereafter, control subjects crossed over to initiate the study treatment and touch-up with post-treatment follow-up identical to the treatment group.

All subjects continued through an extended follow-up period, which consisted of safety and effectiveness follow-up visits at 6, 9, 10, and 12 months after their last treatment, or until the visit at which the Independent Evaluating Investigator's assessment of the subject's overall NLF severity was significantly lower (p < 0.001) than the baseline score, whichever occurred first. Subjects who were eligible for a repeat treatment, with post-treatment follow-up up to 6 months after repeat treatment, at which time all subjects completed follow-up.

**Study Endpoints**

The primary effectiveness endpoint for the study was the blinded Evaluating Investigator’s assessment of the subject’s overall Lip Fullness Scale (LFS) during the follow-up period. No response in the LFS. Effectiveness was demonstrated if at least 60% of subjects treated with JUVÉDERM® Ultra were observed to be responders and if the responder rate for treated subjects was statistically superior to the responder rate for the no-treatment control group at 3 months after treatment.

<table>
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<tr>
<th>Table 11. Subject Assessment of Procedural Pain Scores (N = 36)</th>
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<tbody>
<tr>
<td><strong>JUVÉDERM® Ultra XC</strong></td>
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<tr>
<td><strong>JUVÉDERM® Ultra without lidocaine</strong></td>
</tr>
<tr>
<td><strong>No difference between products</strong></td>
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</tbody>
</table>

**Table 12. Subject Assessments of Comparative Procedural Pain Score**

<table>
<thead>
<tr>
<th>JUVÉDERM® Ultra XC</th>
<th>JUVÉDERM® Ultra without lidocaine</th>
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</thead>
<tbody>
<tr>
<td><strong>No difference between products</strong></td>
<td>2.8</td>
</tr>
<tr>
<td><strong>JUVÉDERM® Ultra were significantly more painful</strong></td>
<td>2.9</td>
</tr>
</tbody>
</table>

The pain scores for the NLFs treated with JUVÉDERM® Ultra XC were significantly lower (p < 0.001) than for the NLFs treated with JUVÉDERM® Ultra without lidocaine (Table 11) based on the 11-point scale. On the comparative scale, 94% (34/36) of subjects treated with JUVÉDERM® Ultra XC compared with JUVÉDERM® Ultra without lidocaine (Table 12)
At Month 3, improvements in upper and lower lip fullness were observed in 75.4% (104/138) and 79.9% (107/134), respectively, based on Evaluating Investigator assessments. While the responder rates for improvement in perilyngeal and oral comissures at Month 3 were 47.3% (62) and 47.3% (65) (114/241), respectively, demonstrating some improvement in severity of upper perilyngeal perioral lines and oral comissures, inadequate information was available regarding the clinical and statistical significance of this improvement. Thus, the treatment benefit for perilyngeal oral and comissures was not determined in lip augmentation study.

At Month 3, 81.8% (112/138) of subjects rated that their overall lip fullness goals were achieved, and 87.5% (118/136) of subjects assessed their treatment outcome as expected or better than expected. The majority of subjects (89.1%, 123/138) indicated willingness to undergo treatment again at Month 3, which remained high at the end of the extended follow-up period, with 84.7% (72/85) indicating willingness to undergo treatment again. Using the Other Aesthetic Features questionnaire, Evaluating Investigators assessed their satisfaction with the subject’s lips and mouth area, with over 75% of subjects assessed as improved through Month 12.

At 3 months, 92.1% (128/139) of subjects rated an improvement in overall satisfaction with the look and feel of their lips and mouth, which lasted through Month 12 for 18.4% (64/74) of subjects. The majority of subjects also reported improvement in the softness, smoothness, and natural look and feel of their lips and mouth through 12 months.

Objective lip measurements calculated from the 3D imaging showed an increase in both lip volume and overall lip surface area. At Month 3, treatment group subjects showed a mean increase in lip volume of 0.61 cc and a 25% increase in overall lip surface area (N = 130), while control group subjects showed almost no increase in lip volume and an 8% increase in surface area (N = 78). Treatment group responders showed an increase in these measurements at later time points that gradually tapered off to a mean lip volume increase of 0.54 cc and a 19% surface area increase at Month 12 (N = 54).

No differences in overall lip fullness responder rates at Month 3 were observed based on the following subgroup analyses: baseline lip fullness, gender, race, investigational site, plane of injection, and statistical significance of this improvement. Thus, the treatment benefit for perilyngeal oral and comissures was not determined in lip augmentation study.

B. INSTRUCTIONS FOR USE

A. To Attach Needle to Syringe

STEP 1: Remove the needle cap

Hold syringe and pull tip cap off the syringe as shown in Figure A.

STEP 2: Insert needle

Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull the needle into the syringe hub as shown in Figure B.

STEP 3: Tighten the needle

Tighten the needle by turning it firmly in a clockwise direction (see Figure C) until it is seated in the proper position.

NOTE: If the position of the needle cap is as shown in Figure D, it is not attached correctly. Continue to tighten until the needle is seated in the proper position.

STEP 4: Remove the needle cap

Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull the needle out of the syringe hub (Figure D).

B. Health Care Professional Instructions

1. JUVÉDERM® Ultra XC injectable gel is a highly cross-linked gel formulation that can be injected using a fine gauge (e.g., 30-G) needle for more versatility in contouring and volumizing of facial wrinkles and folds and lips.

2. Prior to treatment, the patient’s medical history should be obtained, and the patient should be fully apprised of the indications, contraindications, warnings, precautions, treatment responses, adverse reactions, and method of administration.

3. The patient’s soft-tissue deficiencies should be characterized with regard to elasticity, denseness, stress at the injection, and depth of lesion. Depending on the type of skin, best results are obtained when the defect is readily discernible and correction can be visualized by manipulation (stretching) of the skin. Pretreatment photographs are recommended.

4. Although study results showed JUVÉDERM® Ultra XC to be less than 5% greater than JUVÉDERM® Ultra in the lips, 79.9% (107/134) of subjects indicated willingness to undergo treatment again.

5. At 12 months, 89.1% (123/138) of subjects reported improvement through 12 months (Table 14), and 79.9% (107/134) of subjects indicated willingness to undergo treatment again. Using the Other Aesthetic Features questionnaire, Evaluating Investigators assessed their satisfaction with the subject’s lips and mouth area, with over 75% of subjects assessed as improved through Month 12.

6. The patient’s soft-tissue deficiencies should be characterized with regard to elasticity, denseness, stress at the injection, and depth of lesion. Depending on the type of skin, best results are obtained when the defect is readily discernible and correction can be visualized by manipulation (stretching) of the skin. Pretreatment photographs are recommended.

7. The injection technique for wrinkles, folds, and lips may vary with regard to the angle and orientation of the bovel, the depth of injection, and the quantity administered. A linear threading technique, serial puncture injections, taping technique, cross-hatching technique, or a combination have been used to achieve optimal results. Injecting the product too superficially may result in visible lumps and/or discoloration.

8. JUVÉDERM® Ultra XC by applying even pressure on the plunger, and never pulling the needle backwards. It is important that the injection be stopped just before the needle is pulled out of the skin to prevent material from leaking out or causing discomfort to the patient.

9. If the needle is blocked, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle.

10. The typical total volume to achieve optimal correction of the moderate to severe nasolabial folds is 1.6 mL per treatment site. The typical volume to achieve optimal correction for treatment sites is 1-2 mL per site.

11. The typical volume injected into the lips and perioral area to achieve optimal correction for lip augmentation is approximately 0.7-2 mL per site.

12. Correct to 100% of the desired volume effect. Do not overcorrect. The degree and duration of the correction depends on the site being treated, the tissue thickness of the implant site, the depth of the implant in the tissue, and the injection technique. Markedly indurated defects may be difficult to correct.

13. If immediate blanching occurs, the injection should be stopped and the area massaged until it returns to a normal color. Blanching in normal or abnormal subcutaneous injection. If blanching in normal or abnormal subcutaneous injection. If blanching does not return, do not continue with the injection. Treatment with acetaminophen or topical anesthetic cream may be used for additional pain management during and after injection.

14. Injection sites may have mild to moderate injection site responses, which typically resolve in a few days in the NLFS, and within 2 weeks in the lips and perioral area. If the treated area is swollen immediately after the injection, an ice pack can be applied to the site for a short period.
17. After the initial treatment, an additional treatment (from 1 to 4 weeks later) may be necessary to achieve the desired level of correction. If further treatment is needed, the same procedure should be repeated until a satisfactory result is obtained. The need for an additional treatment may vary from patient to patient and is dependent upon a variety of factors such as treatment goals, wrinkle severity, lip fullness, skin elasticity, and dermal thickness at the treatment site.

18. The health care professional should instruct the patient to promptly report to her/him any evidence of problems possibly associated with the use of JUVÉDERM® Ultra XC.

C. Patient Instructions
It is recommended that the following information be shared with patients:

- Within the first 24 hours, patients should avoid strenuous exercise, extensive sun or heat exposure, and alcoholic beverages. Exposure to any of the above may cause temporary redness, swelling, and/or itching at the injection sites.
- To report an adverse reaction, phone the Allergan® Product Support Department, 1-877-345-5372.

9. HOW SUPPLIED
JUVÉDERM® Ultra XC injectable gel is supplied in individual treatment syringes with 30-G needles for single-patient use and ready for injection (implantation). The volume in each syringe is as stated on the syringe label and on the carton. The contents of the syringe are sterile and non-pyrogenic. Do not resterilize. Do not use if package is opened or damaged.

10. SHELF LIFE AND STORAGE
JUVÉDERM® Ultra XC injectable gel must be used prior to the expiration date printed on the label.

Store at room temperature (up to 25°C/77°F). DO NOT FREEZE.

JUVÉDERM® Ultra XC injectable gel has a clear appearance. In the event that a syringe contains material that is not clear, do not use the syringe; notify Allergan® Product Support immediately at 1-877-345-5372.

To place an order, contact Allergan® at 1-800-377-7790.