27 73 70 68

Juvéderm
ULTRA PLUS®

注射用交联透明质酸钠凝胶

2 x 0,8mL

Allergan

72875CH14
Revision 2020-03-03

Allergan
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Caution: The use of the device is limited to licensed physicians or practitioners in medical institutions formally approved by the government with a professional training certificate issued by the manufacturer or its entrusted/ designated institutions in strict accordance with the Instructions for Use.

BEFORE USING PRODUCT, READ THE FOLLOWING INFORMATION THOROUGHLY.

COMPOSITION

Hyaluronic Acid gel	24 mg
Phosphate buffer pH 7.2 q.s.	1 mL

One syringe contains 0.8 mL of ***Juvéderm ULTRA PLUS®***
*including 5 % of uncrosslinked Hyaluronic Acid.

1. DEVICE DESCRIPTION

Juvéderm ULTRA PLUS® injectable gel is a sterile, biodegradable, nonpyrogenic, viscoelastic, clear, colorless, homogeneous gel implant. ***Juvéderm ULTRA PLUS®*** injectable gel consists of cross linked hyaluronic acid (HA) produced by *Streptococcus* bacteria. The gel is presented in a graduated pre-filled disposable syringe. Each box contains two 0.8 mL ***Juvéderm ULTRA PLUS®*** syringes, 4 single-use 27G1/2" sterile needles to be used only for injecting ***Juvéderm ULTRA PLUS®***, an instruction leaflet and a set of labels in order to ensure traceability.
The content of ***Juvéderm ULTRA PLUS®*** syringes is sterilized by moist heat. The 27G1/2" needles are sterilized by radiation.

2. INTENDED USE/INDICATIONS

Juvéderm ULTRA PLUS® injectable gel is indicated for injection into the mid to deep dermis for correction of severe nasolabial folds.

3. CONTRAINDICATIONS

• ***Juvéderm ULTRA PLUS®*** injectable gel is contraindicated for patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
• ***Juvéderm ULTRA PLUS®*** injectable gel contains trace amounts of gram-positive bacterial proteins and is contraindicated for patients with a history of allergies to such material.

4. WARNINGS

• ***Juvéderm ULTRA PLUS®*** injectable gel must not be injected into blood vessels. Introduction of ***Juvéderm ULTRA PLUS®*** injectable gel 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soft tissue fillers, for example, after insertion of the needle, and just before injection, the plunger rod can be withdrawn slightly to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 of shortly after the procedure. Patients should receive prompt medical attention and possibly evaluation by an appropriate physician should an intravascular injection occur. (See Physician Instructions #10)
• Use of ***Juvéderm ULTRA PLUS®*** injectable gel 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 procedure reaction to ***Juvéderm ULTRA PLUS®*** injectable gel has been observed as consisting mainly of short-term inflammatory symptoms starting early after treatment and with less than 7 days' duration. Refer to the SIDE EFFECTS section for details.

5. PRECAUTIONS

• ***Juvéderm ULTRA PLUS®*** injectable gel 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 physicians who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
• Physicians 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 of ***Juvéderm ULTRA PLUS®*** injectable gel for the treatment of anatomic regions other than severe nasolabial folds have not been established in controlled clinical studies.
• As with all transcutaneous procedures, ***Juvéderm ULTRA PLUS®*** injectable gel implantation carries a risk of infection. Standard precautions associated with injectable materials should be followed.
• ***Juvéderm ULTRA PLUS®*** 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 of ***Juvéderm ULTRA PLUS®*** injectable gel for use during pregnancy, in breastfeeding females, or in

patients under 18 years has not been established.
• The safety of ***Juvéderm ULTRA PLUS®*** injectable gel in patients with known susceptibility to keloid formation, hypertrophic scarring, and pigmentation disorders has not been studied.
• ***Juvéderm ULTRA PLUS®*** injectable gel 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 PLUS®*** 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 immediately.
• If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with ***Juvéderm ULTRA PLUS®*** injectable gel, there is a possible risk of eliciting an inflammatory reaction at the implant site. This also applies if ***Juvéderm ULTRA PLUS®*** injectable gel 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.
• In the China registration trial, the primary efficacy endpoint was measured for up to 6 months; the majority of Chinese subjects showed continued clinically meaningful improvement over baseline at 6 months.
• It is recommended that the maximum injection volume of ***Juvéderm ULTRA PLUS®*** injectable gel is 1.5 mL per NLF for initial injection and 0.5 mL per NLF for touch-up injection (4 weeks later after initial injection) which is needed for optimal correction based on China clinical study.

6. SIDE EFFECTS

• Injection procedure reactions to ***Juvéderm ULTRA PLUS®*** injectable gel has been observed as consisting mainly of short-term inflammatory symptoms such as swelling, induration, pain, bumps, redness, bruising and itching.
Subjects mainly had mild to moderate injection-site responses. All injection site reactions completely resolved without medical intervention.

7. INSTRUCTIONS FOR USE

A. To Attach Needle to Syringe

STEP 1: Remove tip cap
Hold syringe and pull tip cap off the syringe as shown in Figure A.

Figure A

STEP 2: Insert needle
Hold the syringe body and firmly insert the hub of the needle (provided in the ***Juvéderm***® package) into the LUER-LOK® end of the syringe.

STEP 3: Tighten the needle
Tighten the needle by turning it firmly in a clockwise direction (see Figure B) until it is seated in the proper position, as shown in Figure C.

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.

Figure B

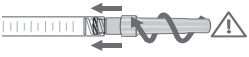
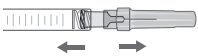


Figure C

Figure D

STEP 4: Remove the needle cap
Hold the syringe body in one hand and the needle cap in the other. Without twisting, pull in opposite directions to remove the needle cap as shown in Figure E.

Figure E



B. Physician Instructions

1. ***Juvéderm ULTRA PLUS***® injectable gel is a highly crosslinked formulation that can be injected using a 27-G needle for more versatility in contouring and volumizing of severe nasolabial folds. Prior to treatment with ***Juvéderm ULTRA PLUS***® injectable gel, 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. Patients also should be advised that supplemental "touch-up" implantations may be required to achieve and maintain maximum correction.
2. The patient's soft-tissue deficiencies should be characterized with regard to etiology, distensibility, stress at the site, and depth of lesion. Depending on the type of skin, best results are obtained when the defect is readily distensible and correction can be visualized by manual manipulation (stretching) of the skin. Pretreatment photographs are recommended.

3. Topical or injectable anesthesia may be used to manage pain during and after injection.
4. After ensuring that the patient has thoroughly washed the treatment area with soap and water, the area should be swabbed with alcohol or other antiseptic. Prior to injecting ***Juvéderm ULTRA PLUS®*** injectable gel, depress the plunger rod until the product flows out of the needle.
5. The injection technique of ***Juvéderm ULTRA PLUS®*** injectable gel with regard to the angle and orientation of the bevel, the depth of injection, and the quantity administered may vary. A linear threading technique, serial puncture injections, or a combination of the two have been used to achieve optimal results. If ***Juvéderm ULTRA PLUS®*** injectable gel is injected too superficially, this may result in visible lumps and/or discoloration.
6. Inject ***Juvéderm ULTRA PLUS®*** injectable gel applying even pressure on the plunger rod while slowly pulling the needle backward. The wrinkle should be lifted and eliminated by the end of the injection. It is important that the injection is stopped just before the needle is pulled out of the skin to prevent material from leaking out or ending up too superficially in the skin.
7. If the needle is blocked, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle.
8. The typical total volume of ***Juvéderm ULTRA PLUS®*** injectable gel to achieve optimal correction for initial treatment is limited to 1.5 mL per NLF. The typical volume of ***Juvéderm ULTRA PLUS®*** injectable gel to achieve optimal correction for touch-up injection is limited to 0.5 mL per NLF.
9. Correct to 100% of the desired volume effect. Do not overcorrect. 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. Markedly indurated defects may be difficult to correct
10. If immediate blanching occurs, the injection should be stopped and the area massaged until it returns to a normal color. Blanching may represent a vessel occlusion. If normal skin coloring does not return, do not continue with the injection.
11. When injection is completed, the treated site should be gently massaged so that it conforms to the contour of the surrounding tissues. If overcorrection occurs, massage the area between your fingers or against an underlying superficial bone to obtain optimal results.
12. With patients who have localized swelling, the degree of correction is sometimes difficult to judge at the time of treatment. In these cases, it is better to invite the patient to a touch-up session after 4 weeks.
13. Patients may have mild to moderate injection-site responses, which typically resolve in a few days. If the treated area is swollen immediately after the injection, an ice pack can be applied to the site for a short period.
14. After the initial treatment, an additional treatment of ***Juvéderm ULTRA PLUS®*** injectable gel (from 4 weeks later) may be necessary to achieve the desired level of

correction. If the wrinkle needs further treatment, 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 wrinkle severity, skin elasticity, and dermal thickness at the treatment site.
15. The physician should instruct the patient to promptly report to her/him any evidence of problems possibly associated with the use of ***Juvéderm ULTRA PLUS®*** injectable gel.

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, contact the Allergan Product Support.

8. HOW SUPPLIED
Juvéderm ULTRA PLUS® injectable gel is supplied in individual treatment syringes with 27-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 nonpyrogenic. Do not resterilize. Do not use if package is opened or damaged.

9. SHELF LIFE AND STORAGE
Juvéderm ULTRA PLUS® 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 PLUS® 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.

To place an order, contact Allergan.

Product shelf life: 2 years

Date of manufacture : refer to original label.

Product name:	***Juvéderm ULTRA PLUS®***
Product Model and specifications :	0.8ml/Syringe 2 Syringes / box
Registration certificate number:	GXRI 20153131708
Product technical requirements :	GXRI 20153131708
Manufacturer / Registrant name:	Allergan
Manufacturer / Registrant address:	Route de Promery Zone Artisanale de Pré-Mairy Pringy 74370 Annecy FRANCE
Manufacturing Site address:	Route de Promery Zone Artisanale de Pré-Mairy Pringy 74370 Annecy FRANCE
Manufacturer / Registrant Tel:	+ 33(0) 4 50 27 27 03
Allergan Product Support e-mail:	MedDeviceComplaintsAPAC@Allergan.com
Agent name:	ALLERGAN INFORMATION CONSULTING (SHANGHAI) CO., LTD
Agent Address:	Room 5605, 1266 West Nanjing Road, Jingan District, Shanghai, China 200040
Agent Tel:	021-60329100
Agent Fax:	021-60329104
After-sales service facility:	SINOPHARM GROUP DISTRIBUTION CO.,LTD.
After-sales service Address:	No.270 Mei Yue Road China (Shanghai) Pilot Free Trade Zone 200131
After-sales service Tel:	4001538070
After-sales service Fax:	021-51062770

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注意：该产品仅限于在国家正式批准的医疗机构中由具有相关专业医师资格的人员，经生产厂家或其委托/指定机构的专业培训并获得培训合格证书后，严格按照产品使用说明书的要求进行使用。

在使用本产品之前，请先仔细阅读下列信息：

结构组成：

透明质酸钠凝胶*	24mg
磷酸盐缓冲液Ph 7.2适量至	1mL
每支透明质酸钠凝胶注射器中的装量为	0.8 ml

*包含5%未交联的透明质酸钠凝胶

1. 设备描述

Juvéderm ULTRA PLUS® 注射用交联透明质酸钠凝胶是一种经过灭菌的、可生物降解的、粘弹性、透明无色，均质凝胶植入物。***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶由马链球菌产生的透明质酸（HA）经交联后形成，凝胶封装在一个有刻度的预灌封的一次性注射器中。每个包装盒中含有两支0.8毫升***Juvéderm ULTRA PLUS®*** 注射器、4支一次性仅用于***Juvéderm ULTRA PLUS®*** 注射的27G1/2 "的无菌针头、一份说明书和一套标签以确保可追溯性。
封装了凝胶的注射器已经湿热灭菌。27G1/2"注射针已经伽玛射线辐照灭菌。

2. 适用范围

Juvéderm ULTRA PLUS® 注射用交联透明质酸钠凝胶用于注射到面部真皮组织的中层到深层部位，以纠正重度鼻唇沟皱纹。

3. 禁忌症

- ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸凝胶对有严重过敏反应、过敏史或者多发性过敏史的患者禁用。
- ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶含有极微量的革兰氏阳性细菌蛋白质，对革兰氏阳性细菌蛋白质有过敏史的患者禁用。

4. 警告

- ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶不能注射进血管中，将***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶注射到血管系统可能导致血管栓塞、闭塞、局部缺血或梗死。软组织注射填充剂时要格外小心，例如，插入针头后在注射之前，可以将注射器推杆轻微回抽，以确认针头不在血管内，然后缓慢注射本品，用力应尽可能小。已有与面部血管内注射软组织填充剂相关的罕见严重不良事件的报道，包括一过性或永久性视力受损、失明、脑缺血或脑出血，导致中风、皮肤坏死和对面部支撑结构的损伤。如果患者出现以下任何一种症状，应立即停止注射，其中包括视力改变、中风、皮肤褪色改变、或注射期间或注射刚结束后的异常疼痛。一旦注射到血管内，应由医师对患者进行及时治疗和相关评估。（见医师使用说明#10）
- ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶在拟注射部位出现活动性炎症（各类皮疹，例如囊肿、丘疹、发疹或荨麻疹）或感染时，必须等炎症或感染有效控制或治愈后才能使用。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶注射后早期会出现由于注射操作而引起的短期炎症。此症状持续时间短于7天。有关详细内容，请参考“副作用”部分。

5. 注意事项

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶为一次性使用包装设计。不能重复灭菌使用。如包装已打开或损坏，请勿使用。

• 为了最大限度地减小潜在并发症的风险，本产品只能由经适当培训、有经验，并且了解注射部位及其周围解剖结构的医师使用。

• 鼓励医师在治疗之前与其患者讨论软组织注射的所有潜在风险，并确保患者知道潜在并发症的体征和症状。

• 根据临床前的研究数据，患者使用Juvéderm系列注射用交联透明质酸钠凝胶的剂量应控制在每年每60kg（130磅）体重的患者少于20ml注射量。尚未获得高于此注射量的相关安全性数据和信息。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶在治疗除矫正重度鼻唇沟皱纹的有效性和安全性还未经对照临床试验得到验证。

• 同所有进入皮肤的治疗操作一样，***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶的植入可能带来感染风险。因此在注射操作时，必须遵循植入材料操作的相关注意事项。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶应当根据说明书标注来使用。更改或在说明书标注范围之外的使用可能不利于本产品保持无菌、同质性和产品特征，因此其使用效果将无法得到保证。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶在孕妇、哺乳期妇女和18岁以下患者中使用的安全性尚未得到验证。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶在瘢痕疙瘩、增生性疤痕以及色素性疾病患者中的安全使用尚未得到验证。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶应当特别注意在接受免疫抑制剂治疗的患者中使用。

• 正在接受能延长出血时间药物（例如，阿司匹林、非甾体类抗炎药和华法林）治疗的患者，在注射操作时可能出现注射部位的瘀青或出血加重的情况。

• 在使用之后，注射器和针头可能成为潜在的生物危险品。应当按照规范的医疗操作流程和当地的法规要求来处理和处置这些物品。

• ***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶为透明无色凝胶，不含可见颗粒物。如注射器内容物出现分层和/或浑浊，请勿使用，并立即联系Allergan产品支持部。

• 如果在接受***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶注射治疗后，又接受激光治疗、化学剥脱术或任何其他基于皮肤反应的治疗，则有可能在注射植入部位引发炎症反应的风险。同样，如果在接受上述治疗后，皮肤尚未完全恢复前，接受***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶注射治疗，也有可能在注射植入部位出现炎症反应的风险。

• 如果操作时未能遵循注射针的使用说明，有可能导致针头脱落和/或产品在注射器LUER-LOK®旋锁接口和针头接口处出现渗漏。

• 基于中国注册临床试验数据，主要终点设定在注射后6个月。对比基线，绝大多数中国受试者在研究的主要终点即注射后6个月时仍保持有临床意义的改善。

• 根据中国注册临床试验结果，建议初始注射治疗时，每侧

鼻唇沟皱纹注射量不超过1.5ml。如需要进一步完善治疗效果，可在初始注射治疗后4周进行修饰注射，每侧鼻唇沟皱纹修饰注射量不超过0.5ml。

6. 副作用

注射***Juvéderm ULTRA PLUS®*** 注射用交联透明质酸钠凝胶后，可能会出现短期的与注射治疗有关的反应。可能出现的反应主要包括肿胀、发硬、触痛、肿块、发红、瘀青和瘙痒等。这些与注射部位相关的反应大多数为轻度或中度，所有反应均自行消失，无需采取治疗措施。

7. 使用说明

A. 将针头安装注射器上

第 1 步：拆除注射器顶端盖帽

握住注射器，然后将顶端盖帽从注射器上拔除，如图 A 所示。

Figure A

第 2 步：插入针头

握住注射器，然后将针头接口（包装中提供）准确插入注射器的LUER-LOK®旋锁接口端。

第 3 步：紧固针头

顺时针方向旋转拧紧针头（见图 B）。直到它位于适当的位置为止，如图 C 所示。

注意：如果针头的位置如图 D 所示未能正确安装，则继续拧紧针头，直到它位于准确的位置为止。

Figure B

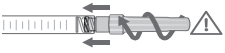


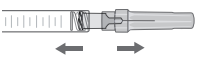
Figure C

Figure D

第 4 步：拆除针头帽

一只手握住注射器，另一只手握住针头帽。在不旋转的状态下向反方向拉动，拆除针头帽，如图 E所示。

Figure E



B. 医师使用说明

1. ***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶是一种高度交联的物质，通过27G的针头注射，用以矫正重度鼻唇沟皱纹。在使用***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶治疗之前，应当详细了解患者的病史，并向患者详细说明产品的适应症、禁忌症、警告、注意事项、治疗反应、副作用以及注射方法等信息。同时也需要告知患者为了达到和维持最佳治疗效果，可能需要进行修饰性注射治疗。

2. 应明确患者软组织缺损的病因、膨胀范围、注射部位张力以及缺损的深度。根据不同类型的皮肤，最佳治疗效果在于缺陷处得到确实的膨胀填充，并且通过检查皮肤（拉伸）可以观察到疗效。建议在注射治疗之前拍摄照片。

3. 可以使用表面麻醉或注射麻醉来缓解注射过程中和注射后的疼痛。

4. 在确定患者已经用肥皂和清水彻底清洗了治疗区域之后，用酒精或其他消毒剂擦拭注射区域。在注射***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶之前，要推动注射器推杆，直到产品从针头处流出为止。

5. ***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶不同的注射方法与倾斜角度和方向、注射深度以及注射量有关。直线注射法、连续多点注射法或两种方法的组合都可用来达到最佳治疗效果。如***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶注射部位太浅，可能导致注射部位出现可见凸起和/或变色。

6. 注射***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶时，在缓慢退针时，均匀推动注射器推杆。皱纹将逐渐被抬起，并在注射结束时消失。需要重点注意的是在针头将从皮肤拔出前停止推注，以防止产品漏出或被注射在皮肤浅层。

7. 如果针头被堵塞，不要持续加压来推动注射器推杆，应停止注射，更换针头。

8. ***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶通常可以实现最佳治疗效果的注射量为每侧鼻唇沟初始注射不超过1.5ml，修饰注射不超过0.5ml。

9. 按照治疗所需容量的100%进行注射。不要超容量注射治疗。治疗效果和疗效持续时间取决于治疗部位缺损的特性、注射部位的张力、产品植入深度以及注射操作方法。 明显硬化的缺陷可能很难治疗。

10. 如果即刻出现皮肤发白，应立即停止治疗，并按摩此区域，直至皮肤恢复正常颜色。皮肤褪色可能表示血管闭塞。如果未能恢复正常肤色，不得继续注射。

11. 当完成注射后，应当温柔地按摩注射部位，来对产品塑形，使其同周围组织契合。如出现注射过量，则在手指之间或在骨骼表面按摩，以实现最佳效果。

12. 对于有局部肿胀的患者，有时很难在注射治疗结束时确定治疗效果。在这些情况下，应当邀请患者在4周后进行修饰注射。

13. 患者可能出现轻度到中度的注射部位反应，此反应通常在几天内缓解。如果在注射之后即刻出现治疗区域肿胀，可以在此部位进行冰敷。

14. 在初始注射后，为达到预期的治疗效果，可能在4周后用***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶进行修饰注射。如果皱纹需要进一步治疗，可以重复相同的治疗过程，直至取得令人满意的结果为止。每位患者对再次治疗的需求可能不同，这取决于各种因素，如皱纹的严重程度、皮肤弹性以及治疗部位的皮肤厚度。

15. 医生应当告知患者，如发现任何可能与***Juvéderm ULTRA PLUS®***注射用交联透明质酸钠凝胶使用的问题，应立即告知医生。

C. 患者使用说明

我们建议患者应当了解下列信息：

- 在接受注射治疗后最初的24h内，患者应当避免剧烈运动、与阳光或热源的过度接触，以及避免接触酒精。与上述任何一种物质的接触都可能导致注射部位的暂时发红、肿胀和/或发痒。
- 需要报告不良事件，请与Allergan产品支持部联系。

8. 供货

Juvéderm ULTRA PLUS®注射用交联透明质酸钠凝胶预灌封于独立包装的注射器中，并配有27G针头用于注射（植入）。每个注射器的容量在注射器及产品盒上标注。注射器中的内容物已经灭菌，且无热原。本品不得重复灭菌。如果包装打开或损坏，请勿使用。

9. 产品有效期及存放

Juvéderm ULTRA PLUS®注射用交联透明质酸钠凝胶应当在产品标识的有效期前使用。

产品室温下存放（最高温度25°C/77°F）。请勿冷冻。

Juvéderm ULTRA PLUS®注射用交联透明质酸钠凝胶外观透明。如注射器中内容物出现浑浊，请勿使用，并立即与Allergan产品支持部门联系。

如需订货，请与Allergan联系。

生产日期：见包装标签

产品有效期：2年

产品名称：	**注射用交联透明质酸钠凝胶**
产品规格：	0.8ml/支　2支/盒
注册证号：	国械注进20153131708
产品标准：	国械注进20153131708
生产企业/注册人名称：	Allergan 艾尔建
生产企业/注册人地址：	Route de Promery Zone Artisanale de Pré-Mairy Pringy 74370 Annecy FRANCE
生产地址：	Route de Promery Zone Artisanale de Pré-Mairy Pringy 74370 Annecy FRANCE
生产企业/注册人电话：	+ 33(0) 4 50 27 27 03
Allergan产品支持邮箱：	MedDeviceComplaintsAPAC@Allergan.com
代理人名称：	艾尔建信息咨询（上海）有限公司
代理人地址：	上海市静安区南京西路1266号56层5605室　邮编：200040
代理人电话：	021-60329100
代理人传真：	021-60329104
售后服务机构：	国药控股分销中心有限公司
售后服务机构地址：	中国（上海）自由贸易试验区美约路270号　邮编：200131
售后服务机构电话：	4001538070
售后服务机构传真	021-51062770

- Do not contain elastomer-rubber latex
- 不含橡胶

- Do not re-use
- 请勿二次使用

- Syringe
- 注射器

- Date of manufacture
- 生产日期

LOT

- Batch code
- 批号

- Temperature limit
- 温度限制

- Attention; see instructions for use
- 注意，参考说明书

- Use-by date
- 有效期至

- Fragile, handle with care
- 易碎，小心轻放

- Needle
- 注射针

- Do not use if package is damaged
- 包装破损切勿使用

- Keep away from sunlight
- 避免日晒

STERILE

- Sterilized using steam or dry heat
- 经湿热（蒸汽）或干热灭菌

REF

- Catalogue number
- 分类编号

- Manufacturer
- 生产企业

STERILE R

- Sterilized using irradiation
- 经辐射灭菌