Juvéderm®

VOLBELLA®

WITH LIDOCAINE

乔雅登® 质颜®

2 x 1mL

Allergan

73573CH10

修订日期：2021-05-20

Allergan

Route de Promery
Zone Artisanale de Pré-Mairy
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Only for professional use

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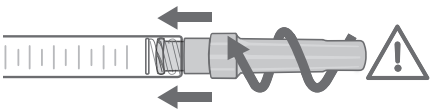

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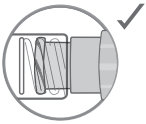

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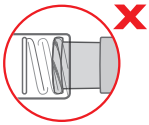

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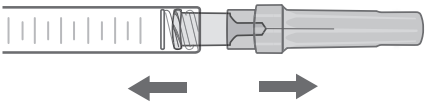

Caution: The use of the device is limited to licensed physicians or practitioners at medical institutions formally approved by the government and with a professional training certificate issued by the manufacturer, or its entrusted/designated institutions, in strict accordance with the Instructions for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

COMPOSITION

Hyaluronic Acid gel*	15 mg
Lidocaine hydrochloride	3 mg
Phosphate buffer pH 7.2 q.s.	1 mL

One syringe contains 1mL of ***Juvéderm® VOLBELLA® with Lidocaine***.
*including 0,95 % uncrosslinked Hyaluronic Acid

DESCRIPTION

Juvéderm® VOLBELLA® with Lidocaine is a sterile pyrogen-free physiological solution of cross-linked hyaluronic acid which is not of animal origin. The gel is presented in a graduated, pre-filled, disposable syringe. Each box contains two 1 mL ***Juvéderm® VOLBELLA® with Lidocaine*** syringes, 4 single-use 30G1/2" sterile needles to be used only for injecting ***Juvéderm® VOLBELLA® with Lidocaine***, an instruction leaflet and a set of labels in order to ensure traceability.

STERILISATION

The contents of the ***Juvéderm® VOLBELLA® with Lidocaine*** syringes is sterilised by moist heat.
The 30G1/2" needles are sterilised by radiation.

INDICATIONS

• ***Juvéderm® VOLBELLA® with Lidocaine*** is an injectable implant use to correct lip structural defects such as asymmetry, contour deformities, volume loss, etc, via mucosa and superficial dermis or mid-dermis injection of lip vermilion body and vermilion border.
• The presence of lidocaine is meant to reduce the patient's pain during treatment.

CONTRA-INDICATIONS

• Do not inject ***Juvéderm® VOLBELLA® with Lidocaine*** into the eyelids and any other parts outside the indications.
• Do not inject into the blood vessels (intravascular). Intravascular injection may lead to embolization, occlusion of the vessels, ischemia or infarction.
• Do not overcorrect.
• ***Juvéderm® VOLBELLA® with Lidocaine*** must not be used in:
- Patients suffering from untreated epilepsy;
- Patients who tend to develop hypertrophic scarring;
- Patients with known hypersensitivity to hyaluronic acid and/or to gram positive bacterial proteins as hyaluronic acid is produced by *Streptococcus* type bacteria;
- Patients with known hypersensitivity to lidocaine or to

amide-type local anaesthetics;
- Patients suffering from porphyria;
- Women who are pregnant or breastfeeding;
- Children.

• ***Juvéderm® VOLBELLA® with Lidocaine*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes, etc.).

• ***Juvéderm® VOLBELLA® with Lidocaine*** should not be used simultaneously with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

• ***Juvéderm® VOLBELLA® with Lidocaine*** is indicated only for mucosa and superficial dermis or mid-dermis injection of lip vermilion body and vermilion border.

• Medical practitioners must take into account the fact that this product contains lidocaine.

• ***Juvéderm® VOLBELLA® with Lidocaine*** is not intended for use in breast augmentation/reconstruction.

• As a matter of general principle, injection of a medical device is associated with a risk of infection. Standard precautions associated with injectable materials shall be followed.

• There is no available clinical data about injection of ***Juvéderm® VOLBELLA® with Lidocaine*** into an area which has already been treated with a non-ALLERGAN dermal filler.

• It is recommended not to inject into a site which has been treated with a permanent implant.

• No clinical data is available regarding the efficiency and tolerance of ***Juvéderm® VOLBELLA® with Lidocaine*** injections in patients having a history of, or currently suffering from, autoimmune disease or autoimmune deficiency or being under immunosuppressive therapy. The medical practitioner shall 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 ensure the specific monitoring of these patients. In particular, it is recommended that these patients undergo a preliminary skin testing for hypersensitivity, and to refrain from injecting the product if the disease is active.

• There is no available clinical data concerning the tolerance of ***Juvéderm® VOLBELLA® with Lidocaine*** injection in patients presenting a history of severe and/or multiple allergies. The medical practitioner shall therefore decide on the indication on a case-by-case basis, according to the nature of the allergy, and shall also ensure the specific monitoring of these at-risk patients. In particular, the decision may be taken to propose a skin testing for hypersensitivity or suitable preventive treatment prior to any injection. In case of history of anaphylactic shock, it is recommended not to inject the product.

• Patients showing a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be

subjected to a skin testing for hypersensitivity before any injection is administered. In the event of acute rheumatic fever with heart complications, it is recommended not to inject the product.

• Patients on anti-coagulation medication or using substances that can prolong bleeding (warfarin, acetylsalicylic acid, nonsteroidal anti-inflammatory drugs, or other substances known to increase coagulation time such as herbal supplements with garlic or ginkgo biloba, etc.) must be warned of the potential increased risks of bleeding and haematomas during injection.

• There is no data available regarding the safety of injecting greater amount than 20 mL of Juvéderm® dermal fillers per 60 kg (130 lbs) body mass per year. This value is based on sub-chronic and chronic toxicity pre-clinical studies, as well as FDA's Guidance for industry for determining the human equivalent dose based on the dose applied to the animals.

• Due to presence of lidocaine, the combination of ***Juvéderm® VOLBELLA® with Lidocaine*** with certain drugs that reduce or inhibit hepatic metabolism (cimetidine, beta-blockers, etc.) is not recommended.

• Due to presence of lidocaine, ***Juvéderm® VOLBELLA® with Lidocaine*** should be used with caution in patients showing symptoms of cardiac conduction disorders.

• Please recommend that the patient not use any makeup during the 12 hours following the injection treatment and that any extended exposure to the sun, UV rays and temperatures below 0°C be avoided, as well as any sauna or hammam sessions during the two weeks following the injection treatment.

• The composition of this product is compatible with fields used for magnetic resonance imaging.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. ***Juvéderm® VOLBELLA® with Lidocaine*** should therefore never be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.

There is no known interaction with other local anaesthetics.

UNDESIRABLE EFFECTS

The patients must be informed that there are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. These include, but are not limited to:

• Inflammatory reactions (redness, oedema, erythema, etc.) which may be associated with itching and/or pain on pressure and/or paresthesia, occurring after the injection. These reactions may last for a week. In particular, it has to be noticed that injection in the mucous membrane may cause more oedema and bruising due to the specific physiology of these tissues. Besides, a preventive anti-inflammatory treatment by a medical practitioner can be recommended.

• Haematomas.
• Induration or nodules at the injection site.
• Staining or discolouration of the injection site might be observed, especially when HA dermal filler is injected too superficially and/or in thin skin (Tyndall effect).
• Poor effect or weak filling 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, cerebral ischemia or cerebral hemorrhage, leading to stroke, skin necrosis and damage to underlying structures. Immediately stop the injection if a patient exhibits any of the following symptoms, including changes in the vision, signs of 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 medical practitioner specialist should an intravascular injection occur. Abscesses, granuloma and immediate or delayed hypersensitivity after hyaluronic acid and/or lidocaine injections have also been reported. It is therefore advisable to take these potential risks into account.
• Patients must report inflammatory reactions which persist for more than one week, or any other side effect which develops, to their medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.
• Any other undesirable side effects associated with injection of ***Juvéderm® VOLBELLA® with Lidocaine*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE – POSOLOGY

• This product is designed to be injected into the dermis or the mucous membrane of the lips by an authorized medical practitioner in accordance with local applicable regulation. In order to minimize the risks of potential complications and as precision is essential to a successful treatment, the product should be only used by medical practitioners who have appropriate training and experience in injection techniques for enhancement and pouting of the lips. They have to be knowledgeable about the anatomy at and around the site of injection.
• Use of the supplied 30G1/2" needle is recommended. However, depending on the medical practitioner's preferred injection technique, it is possible to use a 30G sterile cannula (please refer to the list hereunder). Choice of cannula length is determined by the user according to his/her injection technique.

Material Number	Description
94323/ HPC30019ACSH	Easyflow System-20* cannula 30G x 19mm.
94324/ HPC30025ACSH	Easyflow System-20* cannula 30G x 25mm.

• Contra-Indications, Method of use, Precautions for use and Warnings defined for the needle in this leaflet apply also to the cannula referenced above if used with this product.
• ***Juvéderm® VOLBELLA® with Lidocaine*** 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.
• Prior to treatment, medical practitioners shall inform their patients about the product's indications, contra-indications, incompatibilities and potential undesirable effects/risks associated with dermal fillers injection and ensure that patients are aware of signs and symptoms of potential complications.
• The area to be treated should be disinfected thoroughly prior to the injection.
• Remove tip cap by pulling it straight off the syringe as shown in fig. 1. Then firmly push the needle provided in the box (fig. 2) into the syringe, screwing it gently clockwise. Twist once more until it is fully locked and has the needle cap in the position shown in fig. 3. If the needle cap is positioned as shown in fig. 4, it is incorrectly attached. Next, remove the protective cap by holding the body of the syringe in one hand, the protective cap in the other, as shown in fig. 5, and pulling the two hands in opposite directions.
Prior to injecting, depress the plunger rod until the product flows out of the needle.
Inject slowly and apply the least amount of pressure necessary.
If the needle is blocked, do not increase the pressure on the plunger rod. Instead, stop the injection and replace the needle.
Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level and/or increase the risk of vascular compromise.
• After needle insertion and before injection, it is recommended to withdraw slightly the plunger to aspirate and verify the needle is not intravascular (note that withdrawing the plunger to aspirate will reduce the risk of intravascular injection, however, it will not eliminate the risk completely).
• If immediate blanching occurs at any time during the injection, the injection should be stopped and appropriate action taken such as massaging the area until its return to a normal color.
• 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. The amount injected will depend on the areas which are to be corrected based on the experience of the medical practitioner.
• Do not overcorrect as injection of an excessive volume can be at the origin of some side effects such as tissue necrosis and oedema.

• A touch up (for achieving optimal correction) and/or a repeat (for maintaining optimal correction) treatment with ***Juvéderm® VOLBELLA® with Lidocaine*** might be required.
• It is recommended to wait until side effects are resolved (with a minimal interval of 1 month) between two injections.
• It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.
• The recommended combined maximum volume for initial and touch-up is not over 4.0 mL.
- In the China registration trial, the primary efficacy endpoint was measured for up to 3 months; the majority of Chinese subjects showed continued clinically meaningful improvement over baseline at 3 months.
- For the touch-up injection in China study, it happens at Month 1 after the initial treatment to meet the optimal outcome.
- In the China study, the observed maximum initial volume was 2.8 mL (upper lip 1.4 mL and lower lip 1.4 mL) and the observed combined maximum volume for initial and touch-up volume was 3.9 mL (upper lip 2.3 mL and lower lip 2.1 mL).

WARNINGS
• Check the expiry date on the product label.
• In the event that the content of a syringe shows signs of separation and/or appears cloudy, do not use the syringe.
• Do not re-use. Sterility of this device cannot be guaranteed if the device is re-used.
• Do not re-sterilise.
• For the needles (CE0123 TSK Laboratory, Japan):
- Used needles must be thrown away in the appropriate containers. Do the same for the syringes. Please consult the current applicable directives to ensure their correct elimination.
- Never try to straighten a bent needle; throw it away and replace it.

TRANSPORTATION & STORAGE CONDITIONS
• Transport and store between 2°C and 25°C.
• Fragile.

PRODUCT SHELF-LIFE: 2 years

Product name:	***Juvéderm® VOLBELLA® with Lidocaine***
Product model and specification:	1mL/syringe, 2 syringes/box
Registration certificate no.:	GXRI20213130109
Product technical requirement no.:	GXRI20213130109
Manufacturer name/ Registrant name:	ALLERGAN
Manufacture registered address:	Route de Promery, Zone Artisanale de Pré-Mairy-PRINGY 74370 ANNECY, FRANCE
Manufacture site:	Route de Promery, Zone Artisanale de Pré-Mairy-PRINGY 74370 ANNECY, FRANCE
Manufacture Tel:	+33 (0) 4 50 27 27 03
Agent name:	Allergan (Chengdu) Medical Aesthetic Clinic Co., Ltd.
Agent Address:	RM 3201, Floor 32, Building 3, North Tianfu Road, No.1199, Gaoxin District, Chengdu City, Sichuan Province, China
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
After-sales service Tel:	4001538070
After-sales service Fax:	021-51062770
Manufacturing date:	see the label 
Expiry date :	see the label 

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仅限专业人员使用

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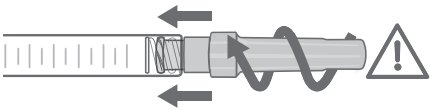

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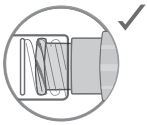

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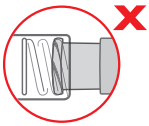

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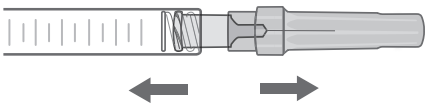

注意：该产品仅限于在国家正式批准的医疗机构中由具有相关专业医师资格的人员，经生产厂家或其委托/指定机构的专业培训并获得培训合格证书后，严格按照产品使用说明书的要求进行使用。

成分

透明质酸钠*	15 mg
盐酸利多卡因	3 mg
磷酸盐缓冲液pH 7.2 q.s.	1 mL

1支注射器内含1 mL的***Juvéderm® VOLBELLA® with Lidocaine。***

*包括0.95%的非交联透明质酸钠

说明

***Juvéderm® VOLBELLA® with Lidocaine*为无菌、非热原、非动物源性的交联透明质酸凝胶植入物。透明质酸凝胶预灌装在有刻度的一次性使用注射器中备用。每个包装盒内有2支1mL *Juvéderm® VOLBELLA® with Lidocaine*的注射器、4支用于注射*Juvéderm® VOLBELLA® with Lidocaine*的一次性使用30G1/2″注射针、一份说明书及可追踪的产品标签。**

灭菌

Juvéderm® VOLBELLA® with Lidocaine注射器内容物采用湿热灭菌。

30G1/2″注射针为辐射灭菌。

适应范围

该产品通过注射至唇红体和唇红缘的唇粘膜、真皮浅层或中层，以矫正唇部不对称、轮廓畸形和容积缺损等结构缺陷。利多卡因可减轻治疗过程中患者的疼痛。

禁忌症

• 不得将***Juvéderm® VOLBELLA® with Lidocaine***注射到眼睑等适应范围规定之外的其他部位。

• 不得将本品注射到血管中（血管内注射）。血管注射可能导致栓塞、血管阻塞、局部缺血或梗死。

• 不得过度矫正。

• ***Juvéderm® VOLBELLA® with Lidocaine***不得用于：

- 患有未治疗的癫痫症患者；
- 有增生性疤痕体质的患者；
- 已知对透明质酸和/或革兰式阳性菌过敏的患者，因为透明质酸是由马链球菌发酵制成；
- 已知对利多卡因或酰胺型局部麻醉药过敏的患者；
- 卟啉症患者；
- 妊娠期或哺乳期妇女；
- 儿童。

• ***Juvéderm® VOLBELLA® with Lidocaine***不得用于皮肤发炎和/或感染（痤疮、疱疹等）区域。

• ***Juvéderm® VOLBELLA® with Lidocaine***不得同激光治

疗、化学深层剥脱或皮肤磨削术同时使用。对于浅层换肤治疗，如出现严重炎症，建议应避免注射本品。

使用注意事项

• ***Juvéderm® VOLBELLA® with Lidocaine***的适应症仅唇红体和唇红缘的唇粘膜、真皮浅层或中层注射使用。
• 临床操作者必须考虑到本产品含有利多卡因。
• ***Juvéderm® VOLBELLA® with Lidocaine***禁止用于隆胸/乳房再造注射。
• 根据常规原则，需要考虑医疗器械的注射操作通常存在感染风险。进行注射材料相关操作应遵循标准的预防措施。
• 目前没有***Juvéderm® VOLBELLA® with Lidocaine***注射在已接受过非Allergan公司生产的真皮填充剂注射部位的临床数据。
• 不建议在已经接受过永久性植入物植入的部位进行注射。
• 针对有自身免疫性疾病、免疫缺陷病史的患者或目前有自身免疫性疾病、免疫缺陷，或正在接受免疫抑制治疗的患者注射***Juvéderm® VOLBELLA® with Lidocaine***的疗效和耐受性，无可用临床数据。医生应当根据疾病的临床表现和症状和相应的治疗来逐例评估确定适应症，并对这些高危患者进行特定的监测。特别是，建议这些患者接受过敏反应的初步皮肤试验，如果该疾病处于活性状态，则避免注射本品。
• 针对有严重和/或多种过敏史的患者注射***Juvéderm® VOLBELLA® with Lidocaine***的耐受性，无可用临床数据。医生应当根据过敏的性质逐例确定适应症，并对这些高危患者进行特定的监测。特别应当在注射前，考虑进行过敏性的皮试或适当的预防治疗。如果患者有过敏性休克病史，不建议注射本品。
• 有链球菌疾病（喉咙反复疼痛、急性风湿热）病史的患者在注射前需进行过敏性的皮试。急性风湿热伴有心脏病患者，不建议注射本品。
• 应警告服用抗凝血药物或使用延长出血物质（华法林、阿司匹林、非甾体抗炎药或其他已知的增加凝血时间，如含蒜或银杏提取物的中药补充剂）的患者，在注射本品时会增加血肿和出血的风险。
• 目前没有关于60kg（130磅）体重患者每年接受ALLERGAN真皮填充剂注射剂量超过20 ml的安全性数据，此数据是根据临床前研究亚慢性和慢性毒性以及美国FDA行业指导原则，通过对作用到动物体内剂量换算为等量人体剂量获得。
• 由于存在利多卡因，***Juvéderm® VOLBELLA® with Lidocaine***不建议与某些降低或抑制肝脏代谢的药物（西咪替丁、β受体阻滞剂）联合使用。
• 由于存在利多卡因，有心脏传导障碍症状的患者应谨慎使用***Juvéderm® VOLBELLA® with Lidocaine***。
• 建议患者不要在注射后12h内化妆。患者应避免长时间暴露于阳光、紫外线及零度以下环境中，2周内应避免使用桑拿房或蒸气室。

• 本品中成分与核磁共振成像具有相容性。

不相容性

因透明质酸与季铵盐（如苯扎氯铵）间的不相容，因此不要将***Juvéderm® VOLBELLA® with Lidocaine***与这类物质或经此类物质处理的医疗器械接触。
尚未知本产品与其他局部麻醉剂的相互作用。

不良反应

医生务必告知患者注射此类填充物的潜在不良反应，可能注射后即刻出现或延迟一段时间后出现。不良反应包括但不局限于下述情况：
• 炎症反应（红肿、水肿、红斑等），可能伴有瘙痒和/或压痛和/或感觉异常，在注射后可能出现。这些反应可能会持续一周。特别要注意的是，由于这些组织的特殊生理作用，在粘膜内注射可能会引起更多的水肿和淤青。此外，建议医生进行预防性抗炎治疗。
• 血肿。
• 注射部位硬化或结节。
• 可能观察到注射部位染色或变色，尤其是透明质酸真皮填充剂被注射到浅表和/或浅层皮肤（丁达尔效应）。
• 填充效果欠佳或疗效不明显。
• 报道的罕见但严重的不良事件与血管内注射真皮填充剂和组织压迫有关，包括暂时性或永久性的视力障碍、失明、脑缺血或脑出血、中风、皮肤坏死和潜在的结构损伤。患者如出现下述的任何症状应立即停止注射，包括视力改变、脑梗塞迹象、皮肤发白或术中或术后不久发生的不正常疼痛。如产品注射到血管，患者应当得到及时的医疗护理，并由合适的医疗专家进行评估。也有报道注射透明质酸和/或利多卡因后出现脓肿、肉芽肿、即时或迟发性过敏反应。因此，建议考虑这些潜在的风险。
• 患者需将一周后仍存在的炎症或其他继发的症状及时报告医生。医生针对这些情况进行适当治疗。
• 请务必将***Juvéderm® VOLBELLA® with Lidocaine***的任何其他不良反应反馈给销售商和/或生产商。

使用方法-剂量要求

• 该产品需依照当地法规要求，由经授权的专业医生在真皮或口唇粘膜内注射。为减少潜在并发症的风险，并且保证精准注射是确保成功注射的关键因素，产品注射应当仅由接受过适当皮肤凹陷填充以及丰唇培训并具有注射技术经验的医生完成。同时要求专业人员需要具有注射部位及其周边的解剖知识。
• 推荐使用供应的30G1/2″ 针头。但是，根据医生偏好的注射技术，可以使用30G灭菌钝针（请参阅下面的列表）。钝针长度的选择由用户根据其注射技术确定。

材料编号	说明
94323/ HPC30019ACSH	Easyflow系统-20*钝针 30G×19 mm。
94324/ HPC30025ACSH	Easyflow系统-20*钝针 30G×25 mm。

• 本说明书中定义的针头禁忌症、使用方法、使用注意事项和警告也适用于上面提到的钝针（如果与本品一同使用）。

• 使用***Juvéderm® VOLBELLA® with Lidocaine***时，不得对原包装产品进行修改。修改原包装或未按使用说明使用本品可能会影响进而无法保证产品的无菌性、均质性和性能。

• 注射治疗前需向患者告知该产品的适应症、禁忌症、不相容性和可能产生的不良反应/与真皮填充剂注射相关的风险，以保证患者了解潜在并发症的迹象及症状。

• 注射治疗前需对注射部位进行彻底消毒。

• 如图1所示，将顶帽从注射器上直接拔出。如图2所示，将包装盒中提供的针头顺时针轻轻地拧到注射器上。拧到完全进入的状态，针帽放置位置如图3所示。图4中的针帽位置是错误的。下一步，一手握住注射器，另一只手握住保护帽，如图5所示，两只手向相反地反向拉动，将保护帽拔下。

• 注射前，将推杆塞压紧，直到产品流出针头。

• 缓慢注射，使用最小的推力。

• 如注射针堵塞，请勿对推杆塞施加更大推力，而应当停止注射并更换针头。

• 若未遵守这些安全措施，可能会造成针头的脱落和/或鲁尔锁接口处产品的泄露和/或增加血管受损风险。

• 针头插入后，在注射前，建议轻轻回抽推杆进行抽吸，确认针头未插入血管（提示回抽对降低栓塞风险有一定作用，而非完全避免）。

• 如注射时出现皮肤发白，应立即停止注射，并采取适当措施，如按摩注射区域直至皮肤恢复正常颜色。

• 矫正程度及持续时间根据治疗缺陷的特点、注射部位的组织应力、植入的深度和注射技术。注射剂量是基于医生的经验而选择的注射区域。

• 请勿过度矫正，注射过量可能引发一些不良反应，如组织坏死和水肿。

• 可能需要注射***Juvéderm® VOLBELLA® with Lidocaine***，进行修饰（达到理想矫正效果）和/或重复治疗（维护理想矫正效果）。

• 建议不良反应消失后（最小间隔为1个月）进行第二次注射。

• 注射后，需按摩治疗部位，使本品均匀分布。

-首次和修饰补充联合注射剂量不超过4mL

-基于中国注册临床试验数据，主要终点设定在注射

后3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3个月时仍保持有临床意义的改善。-关于中国临床试验中的修饰补充注射，修饰补充注射发生在首次注射之后的1个月，以达到理想效果
-在中国临床试验中，观察的最大首次注射剂量为2.8mL（上唇注射剂量为1.4mL,下唇注射剂量为1.4mL）；观察的最大联合注射剂量为3.9mL（上唇注射剂量为2.3mL,下唇注射剂量为2.1mL）

警告
- 检查产品标签上的有效日期。
- 如注射器的内容物发生分离或混浊，请勿使用。
- 请勿重复使用。重复使用不能保证产品的无菌性。
- 请勿重复灭菌。
- 针对注射针头（CE0123 TSK Laboratory, Japan）：

-使用过的注射针头和注射器请务必扔到合适的容器中。请参考适用的规定进行妥善处理。
- 如注射针头弯曲，请勿尝试掰直。请扔掉并更换新针头。

运输和存储条件
- 运输和存储温度：2℃-25℃。
- 易碎品。

货架有效期：2年

产品名称:	含利多卡因注射用交联透明质酸钠凝胶 ***Juvéderm® VOLBELLA® with Lidocaine***
型号、规格:	1mL/支 ,2支/盒
医疗器械注册证编号:	国械注进20213130109
产品技术要求的编号:	国械注进20213130109
生产企业/注册人名称:	ALLERGAN 艾尔建
生产企业/注册人住所:	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
电话:	+33 (0) 4 50 27 27 03
代理人名称:	艾尔建（成都）医疗美容诊所有限公司
代理人住所:	中国（四川）自由贸易试验区成都高新区天府大道北段1199号3号楼32层3201号
电话:	021-60329100
传真:	021-60329104
售后服务单位:	国药控股分销中心有限公司
售后服务单位地址:	中国（上海）自由贸易试验区美约路270号 邮编：200131
电话:	4001538070
传真:	021-51062770
生产日期:	见标签 
失效日期:	见标签 

- Do not contain elastomer-rubber latex
- 不含乳胶

- Do not re-use
- 请勿重复使用

- Syringe
- 注射器

- Date of Manufacture
- 生产日期

- Batch Code
- 批号

- Temperature limit
- 温度限度

- Fragile, handle with care
- 易碎，小心轻放

- Needle
- 注射针

- Do not use if package is damaged
- 包装破坏请勿使用

- Attention; see instructions for use
- 注意；参见说明书

- Use-by date
- 失效日期

- Sterilized using irradiation
- 蒸汽或干热灭菌

- Keep away from sunlight
- 避光保存

- Sterilized using steam or dry heat
- 蒸汽或干热灭菌

- Catalogue number
- 参考编号

- Manufacturer
- 生产企业

Product name: Juvéderm VOLBELLA with Lidocaine
Region: CHINE
SAP number: 73573CH10
Date: 02/06/2021
TQA00117Rev2

FINAL ART

Format : Format ouvert: 225 x 175 mm
Format fermé : 175 x 75 ±1 mm

Façonnage : Brochage piqure point métal / ligne de pli (5±1 mm du coté droit) / la 3ème page de couverture permet la fermeture de la notice

Code barre : Hauteur : 7mm ±1 mm
Longueur : 38mm ±1 mm
Position code barre: 9 ± 1mm du bas de la page
10 ± 1mm du coté gauche

Papier couverture: 115g/m2 Luxosamt Offset
Papier page: 45g/m2 Offset LWC Mat

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Epaisseur maxi: 3mm

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