请仔细阅读使用说明书并按照说明使用

Restylane® DEFYNE®
瑞蓝·定采™

Restylane Defyne

注射用交联透明质酸钠凝胶

Cross-linked Sodium Hyaluronate Gel for Injection

使用说明书

产品名称

通用名：
注射用交联透明质酸钠凝胶
(Cross-linked Sodium Hyaluronate Gel for Injection)

汉语拼音：
ZhuShe Yong Jiaolian TouMingZhiSuan Na NingJiao

型号：Restylane Defyne

规格：1 mL/支, 27G x 1/2”超薄壁，2枚针头

生产企业/注册人

名称：Q-Med AB 中文名：科医有限公司

住所：
Seminariegatan 21, 752 28 Uppsala, Sweden

生产地址：
Seminariegatan 21, 752 28 Uppsala, Sweden

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代理人/售后服务机构

名称：科医国际贸易（上海）有限公司

住所：中国（上海）自由贸易试验区基隆路1号汤臣国际贸易大楼2017室，邮编200131

电话：021-5869 0300

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进口医疗器械注册证号/产品技术要求编号：国械注进20213130059

产品成分

交联透明质酸钠	20 mg/mL
盐酸利多卡因	3 mg/mL
生理缓冲溶液 pH 7	加至足量1mL

产品描述

Restylane Defyne 是一种无菌、透明、可生物降解的凝胶。添加了3mg/mL盐酸利多卡因，凝胶含有非动物源性交联透明质酸钠，在磷酸盐缓冲液中的浓度为20mg/mL。凝胶预装在塑料注射器内并湿热灭菌。注射器与两枚27G x 1/2”超薄壁针头一起单独包装在泡罩内。针头经辐照灭菌。本产品一次性使用。

Restylane Defyne 凝胶粒径分布由显微镜照片法测得的。凝胶颗粒分布应≤7mm。凝胶颗粒测量的是溶胀后的凝胶颗粒。

识别产品真伪：可以通过扫描包装侧面的 UDI 码来查验产品真伪。

若查询结果提示该产品非瑞典Q-Med AB生产的 Restylane Defyne，请勿使用并立刻与代理商或瑞典 Q-Med AB 在中国的售后服务单位——科医国际贸易（上海）有限公司联系。

请指导患者将含有批号、生产日期和失效日期的标签撕下并粘贴在需由患者本人保存的资料上。为了保证追溯性，包装及病历标签需要附在病历上。

若发生不良反应，医生或患者需提供产品型号及批号，以追踪用于患者的产品。

作用机制

Restylane Defyne 是一种组织填充剂，通过填充面部皮肤从而修复皮肤表面轮廓以达到满意的矫正效果。其体积填充及提升能力源于交联透明质酸结合水的能力。添加的利多卡因能够减轻注射期间患者的疼痛。

Restylane Defyne 会在人体内逐渐降解，随之填充效果会逐渐消失。填充效果因人而异，多数情况下能保持6个月以上。希望保持填充效果的患者，可以在治疗效果变得不太明显或消失后再次接受补充注射。

一项在中国进行的临床试验中，受试者鼻唇沟处注射 Restylane Defyne，其中大多数患者的治疗效果可维持6个月以上。

适用范围

Restylane Defyne 适用于面部真皮组织中层至深层填充以纠正中度至重度鼻唇沟皱纹。

注意！注射过程必须严格遵守外科治疗无菌操作原则。只有经过相关培训且经验丰富，以及具有注射部位的解剖知识的医生才能使用该产品。Restylane Defyne 必须由国家行政机构正式批准的医院及医疗美容机构中的整形外科医生、皮肤科医生、美容整形科医生在上述机构中进行注射。这些机构包括已经获取《医疗机构执业许可证》的医疗美容整形诊所、综合医院美容门诊及美容整形专科；整形外科专科医院。上述医生须通过瑞典Q-Med AB在中国的售后服务单位—科医国际贸易（上海）有限公司及其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，才可以开始使用 Restylane Defyne 产品进行治疗。

禁忌症

1.禁用于有严重过敏史的患者，禁用于既往曾有多重严重过敏史的患者。

2.禁用于有链球菌蛋白质过敏史的患者，因产品可能含有微量的该原料。

3.禁用于患有利多卡因及酰胺类局部麻醉剂过敏的患者。

4.以下情况禁止使用本产品：
-该部位已注射永久填充剂或使用过非透明质酸类填充剂
- 既往注射填充剂的种类不明确的部位

5.禁止用于凝血机制异常的患者，或正在接受溶栓治疗或抗凝治疗的患者。

6.治疗部位或附近有活动性疾病，如炎症（皮疹，如囊肿、丘疹、皮疹或荨麻疹）、感染或肿瘤，在得到控制之前，应避免在预期治疗处或其附近使用。

警告

1.Restylane Defyne 仅用于真皮组织内填充以纠正鼻唇沟。本产品不得用于乳房部位注射。

2.切勿注入肌肉或血管。误注入血管或在血管附近注射可能会导致局部浅表坏死和瘢痕，是由血管损伤或阻塞造成。若患者之前曾在目标治疗区域进行过手术，需更为小心。侧支血流量有限的区域会增加缺血的风险。推荐注射前进行回抽。

3.若意外注射软组织填充剂进入面部血管可能导致注射部位栓塞、血管闭塞、局部缺血、坏死或梗塞，或者影响区域血管供血。罕见但严重的不良事件包括暂时或永久视觉障碍、失明、脑缺血或梗死。如果表面皮肤发白（苍白）或者患者抱怨异常疼痛或者出现任何与血管内注射相关症状时，应立即停止注射，专科医生应对这类病人立即进行医疗评估和护理。

4.禁止将 Restylane Defyne 与其它产品混合后注射入人体。

潜在的并发症和副作用

预期注射相关反应

注射后，预期会出现注射相关的反应，如注射部位出现红斑、肿胀、疼痛、瘙痒、淤青或压痛。一般来说，这些反应会在注射后一到两周内自行消退。

上市后的不良事件报告

下述是上市后不良事件报告（非详细清单）。基于全球市场已经使用过的 Restylane Defyne 大致数量，估算出报告频率。

1/1 000 – 1/10 000
- 结节 / 硬结
- 注射后及注射后几周内的肿胀

1/10 000 – 1/100 000
- 淤青 / 血肿
- 色素异常 / 色素沉着
- 眼部异常包括眼干、眼胀、视觉障碍例如失明，短暂性视力模糊，眼睑下垂，流泪增加和视觉敏感度降低
- 红斑
- 凝胶溢出
- 过敏 / 血管性水肿
- 感染和脓肿形成
- 炎症
- 注射部位反应包括：烧灼感、表皮脱落、刺激感、不适感及温热感
- 局部缺血 / 坏死
- 神经学症状包括面神经麻痹、感觉减退和感觉异常
- 非皮肤病学事件包括焦虑、头晕、呼吸困难、头痛、心神不安、恶心、发热和鼻窦炎
- 疼痛 / 触痛
- 丘疹 / 结节
- 瘙痒
- 疤痕 / 结痂 / 皮肤萎缩
- 效果持续时间短

<1/100 000
- 痤疮
- 小水泡 / 水疱
- 毛细血管异常包括毛细血管扩张
- 皮炎
- 皮肤真菌病
- 凝胶移位
- 排出 / 溢出
- 组织包裹
- 肉芽肿 / 异物反应
- 肌肉颤搐、肌无力
- 其他皮肤病学事件包括斑秃、嘴唇干裂、皮肤干燥、皮肤形成皱纹
- 皮疹
- 疱疹感染复发
- 荨麻疹

因不慎注入血管可能会出现血管损伤或因为与其他面部填充剂作用造成血管压迫。这可表现为植入部位或受损血管供血区域出现皮肤苍白、皮肤网状变色、坏死或溃疡，极小可能因栓塞造成其他器官缺血。面部整形造成罕见的严重事件可能会造成暂时或永久视力损伤、失明、大脑缺血或脑梗死。

有报告注射后不久或注射几周后在植入部位出现的炎症症状。在出现原因不明的炎症反应时，应排除感染的可能，并在必要时接受治疗，因为感染治疗不当可能会发展成脓肿形成等并发症。不建议仅使用口服皮质类固醇而不同时接受抗生素治疗。

必须对长时间服用皮质类固醇或抗生素等药物所致的不良事件进行仔细评估，因为这可能会使患者具有某种风险。在出现持续或反复发作的炎症症状时，可考虑通过抽吸/引流、挤压或酶降解（注射透明质酸酶）去除该产品。在进行任何产品去除步骤之前，可使用非甾体抗炎药等药物进行2-7天的治疗或使用糖皮质激素进行7天以下的短期治疗，以减轻肿胀症状，从而更便于对所有残留产品进行触诊。

对于在临床上出现了显著反应的患者，决定进行再治疗时应考虑前次反应的原因及意义。

发生不良事件应向瑞典 Q-Med AB 在中国的售后服务机构——科医国际贸易（上海）有限公司报告。

装配指导

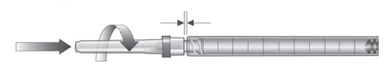
使用无菌的适当针头是很重要的。合适的针(27G x ½”超薄壁)与注射器一起包装在泡罩中提供。

使用外科手套，取下针套的盖子，从注射器上旋下针尖帽。紧紧握住注射器筒，另一只手握住针罩。将针头固定在注射器上，同时用力推动和旋转，直到针头完全锁定。为了确保正确的安装，尽量减少针罩和注射器之间的间隙。参见图1。

在注射前将注射针保护套直接拔出。不得旋转。

注意!不当的组装可能导致泄漏或断针。

图1



使用方法

医生必须在治疗前预先告知患者该产品的适应症、预期治疗效果及效果持续时间、禁忌症、注意事项、警告和可能出现的不良事件。医生也必须在治疗前预先与患者讨论所有软组织填充的潜在风险，请确保患者已经了解潜在并发症的症状和体征。

对于初次注射，建议每侧鼻唇沟使用不超过1.5mL。在鼻唇沟治疗中，初次注射和后续的修复注射之间的时间间隔至少为2周。对于修复注射，建议每侧鼻唇沟使用不超过0.5 mL。

使用适当的消毒液清洁治疗部位，并于干燥后注射。

为了避免针头断裂，在治疗前或治疗期间不要试图弯曲或以其他方式操作针头。如果针头变弯了，请丢弃，然后用一枚同样大小的注射针代替它。注射针的大小和长度会影响推挤力。如果使用较细和/或较长的注射针，注射时的阻力可能过高，导致针头和注射器泄漏或分离的风险增加。

注射前，小心推挤注射器中空气直至针尖部位有小滴的凝胶流出。将注射器转轴对准针头的斜角。

建议注射前先进行回抽以确认注射针没有进入血管内。慢慢地注入少量产品。

用拇指或手掌轻轻按压柱塞棒，注射凝胶。可选择多种注射技术，如连续点状注射、线性注射或联合应用两种注射技术。

任何时候都不得对注射器施加过大的压力。有疤痕组织时，可能会阻碍针头穿透皮肤。遇到阻力时，应将注射针部分撤回，并重新进行定位，或完全撤回注射针，并检查功能。

建议为每个新的治疗部位更换注射针。

每次治疗时，缺陷应当充分矫正，但切勿过度纠正。

明显的硬结可能是很难纠正的。纠正的程度和持续时间取决于治疗的特性、植入部位的组织压力、组织的植入深度和注射技术。

如果皮肤表面转为白色（苍白），应立即停止注射，并对该部位进行按摩直至皮肤颜色恢复正常。苍白可能代表血管堵塞。如果皮肤颜色不能恢复正常，应停止注射。

注射后应对注射部位进行轻柔按摩。

注射后用冰袋短时冷敷注射部位，有助于缓解注射部位的肿胀和不适感。如果冰敷区域仍旧麻木，冰袋要谨慎使用，以避免冻伤。

对治疗效果不满意的患者，可能还需要再进行补充注射以达到理想的治疗效果。

注意！正确的注射技术是治疗成功的关键。关于注射技术及相关培训的详情，敬请咨询瑞典Q-Med AB公司的售后服务单位——科医国际贸易（上海）有限公司。

治疗后所有注射器、注射针及所有注射器中未用完的凝胶必须立即丢弃，并且不得重复使用，因为未用完的产品可能已受到污染，还可能有感染等相关风险。应按照公认的医疗规范和相应的国家、地方或机构指南对其进行处置。针头应该被放置在正规的锐器收集器里。

贮藏条件

低于25°C储存。禁止冷冻，避免阳光照射。

生产日期

见包装上的生产日期信息。

有效期

产品包装所标注的生产日期起24个月。不要在包装上标明的有效期后使用。

包装上标志的意义

LOT	产品批号
	有效期
	生产日期
STERILE	已灭菌。注射器内产品已经高压蒸汽灭菌
STERILE R	辐照灭菌。注射针经辐照灭菌。
REF	针的目录号
	制造商
25°C 2°C	温度限制
	一次性使用
	注意，参考说明书
	避免日晒
	包装破损请勿使用

其他

咨询产品相关信息可与瑞典 Q-Med AB 在中国的售后服务机构——科医国际贸易（上海）有限公司联系，或登陆网站进行查询：www. restylane.com.cn

Restylane、瑞蓝、Restylane Defyne、Defyne 和 Galderma 是注册商标。

注意！在中国销售的 Restylane Defyne 产品必须为瑞典 Q-Med AB 根据中国国家药品监督管理总局的要求特殊包装的，且必须通过瑞典 Q-Med AB 指定的销售渠道购买。

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修订日期：-

90-12466-01

Restylane® DEFYNE®
瑞蓝·定采™

Please read the Instructions for Use carefully, and use the product according to the instructions.

Restylane® DEFYNE®

Cross-linked Sodium Hyaluronate Gel for Injection

INSTRUCTIONS FOR USE

Name
Generic Name: Cross-linked sodium hyaluronate gel for injection

Model: Restylane Defyne

Specification: 1 mL/syringe, 27G x ½ " ultra thin wall (UTW), 2 needles

Manufacturer/Applicant
Name: Q-Med AB 科医有限公司
Registration address:
Seminariegatan 21
752 28 Uppsala
Sweden

Manufacturing address:
Seminariegatan 21
752 28 Uppsala
Sweden

Seminariegatan 31
752 28 Uppsala
Sweden

Phone: +46 18 474 90 00
Fax: +46 18 474 90 01

Agent/After Sales Service Agent
Name:
Q-Med International Trading (Shanghai) Co., Ltd.

Address:
Room 2017, No.1 Ji Long Road, Thomson International Trade Building, Free Trade Zone, 200131, (Shanghai), China

Phone: 021-58690300
Fax: 021-58690300

Registration Certificate Number for Imported Medical Device/Product Technical Requirements Number:
国械注进20213130059

Composition
Cross-linked sodium hyaluronate	20 mg/mL
Lidocaine hydrochloride	3 mg/mL
Phosphate buffered saline pH 7	q.s. ad 1 mL

Description
Restylane Defyne is a sterile, transparent and biodegradable gel. The gel consists of cross-linked sodium hyaluronate of non-animal origin in phosphate buffered saline at a concentration of 20 mg/mL with the addition of 3 mg/mL lidocaine hydrochloride. The gel is supplied in a prefilled plastic syringe. The contents of the syringe are sterilized using moist heat. The syringe is packaged individually in a blister, with two 27G x ½" ultra thin wall needles. The needles have been sterilized using irradiation. The product is for single use only.

The gel particle size for Restylane Defyne is measured on microscopic images. The gel particle length shall be ≤ 7 mm. The gel particles are measured as swelled gel particles.

Identification of Genuine Products: The authenticity of the product can be verified by scanning the UDI code on the side of the package.

Do not use the product if the identification check showed that it is not Restylane Defyne manufactured by the Swedish company Q-Med AB, Sweden. If the product is a counterfeit product, please immediately contact the distributors or Q-Med International Trading (Shanghai) Co., Ltd., the after sales service agent of Q-Med AB.

Please instruct the patients to tear off the part of the carton containing product Lot number, Manufacturing date and Expiry date and keep it in the document kept by the patients themselves.
To ensure traceability the package includes patient record labels that should be attached to patient records.

The model name and lot number must be submitted by doctors or patients when adverse events are reported, in order to trace the product used by patients.

Performance
Restylane Defyne is a tissue filler used to restore the skin contours to the desired level of correction through augmentation of facial skin. The volume and the lifting capacity originate from the ability of cross-linked hyaluronic acid to bind water. The addition of lidocaine provides a pain relieving effect during treatment.
Restylane Defyne will degrade gradually in the body. With degradation the filler effect will disappear. The filler effect may retain for more than 6 months in most cases but varies between individuals. The patients, who want to keep the filler effect, can receive follow-up injections when the filler effect becomes less visible or disappears.
In a clinical study performed in China, where patients were injected with Restylane Defyne in the nasolabial folds, the filler effect remained for more than 6 months in the majority of patients.

Indication
Restylane Defyne should be injected in the mid to deep dermis to correct moderate to severe nasolabial folds.

Note! The injection procedure should strictly follow the rules of aseptic surgical technique. The product should only be used by doctors who have appropriate training, and experience, and who are knowledgeable about the anatomy at and around the site of injection. Injections of Restylane Defyne must only be done by plastic surgeons, dermatologists and cosmetic doctors at hospitals and medical plastic surgery institutions officially approved by the state administrative authorities. These institutions include clinics for medical cosmetic and plastic surgery, medical cosmetic outpatient departments and plastic surgery departments in general hospitals and specialized hospitals for medical cosmetic and plastic surgery, which must have obtained a "Medical Institution Business License". Doctors of those institutions should only use Restylane Defyne after being trained and certified by the after sales service agent of the Swedish company Q-Med AB, Q-Med International Trading (Shanghai) Co., Ltd., and/or its appointed agents. After obtaining the training certificate, the doctors must strictly follow the instructions in this document (Instructions for Use).

Contraindications
1. Do not use in patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies.
2. Do not use in patients with a history of hypersensitivity to streptococcal proteins, as the product may contain trace amounts of such material.
3. Do not use in patients with known hypersensitivity to lidocaine or to amide-type local anaesthetics.
4. Do not use in the following situations:
   - Permanent implant or implant other than hyaluronic acid in the same area
   - If no information is available on the type of implant
5. Do not use in patients with bleeding disorders or patients who are taking thrombolytics or anticoagulants.
6. Use at specific sites where there is active disease, such as inflammation (skin eruption such as cysts, pimples, rashes or hives), infection or tumours, in or near the intended treatment site should be avoided until the underlying process has been controlled.

Warnings
1. Restylane Defyne is only intended for use as an intradermal implant for correction of nasolabial folds. The product should not be used for breast site injections.
2. Do not inject intramuscularly or intravascularly. Localized superficial necrosis and scarring may occur after injection in or near blood vessels. It is thought to result from the injury, obstruction, or compromise of blood vessels. Special caution should be taken if the patient has undergone a prior surgical procedure in the planned treatment area. Areas with limited collateral blood flow has an increased risk of ischemia. Aspiration prior to injection is recommended.
3. Unintentional introduction of soft tissue fillers into the vasculature in the face may lead to embolization, occlusion of the blood vessels, ischemia, necrosis or infarction at the implant site or in the area supplied by the blood vessels affected. Rare but serious adverse events 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 any of the following symptoms occurs, 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 specialist doctor should an intravascular injection occur.
4. This product should not be mixed with other products prior to injection.
5. The product is for single use only. Do not resterilize.
6. Do not use if package is opened or damaged, or if the expiry date or lot number is illegible.

Precautions
1. This product should only be used by doctors who have appropriate training, experience, and knowledge about the anatomy at and around the site of injection in order to minimize the risks of potential complications (e.g. perforation or compression of vessels, nerves and other vulnerable structures).
2. Injection procedures are associated with a risk of infection. Aseptic technique and standard practice to prevent cross-infections are to be followed.
3. Use with caution in patients on immunosuppressive therapy.
4. Avoid injecting into areas in close proximity to permanent implant, as this could aggravate latent adverse events or interfere with the aesthetic outcome of the treatment.
5. Patients who are using substances that may affect platelet function, such as aspirin and non-steroidal anti-inflammatory drugs may, as with any injection, experience increased bruising or bleeding at injection sites.
6. Injection procedures can lead to reactivation of latent or subclinical herpes viral infections.
7. Injecting the product too superficially may result in contour irregularities, visible lumps and/or discoloration.
8. Post inflammatory pigmentation changes may occur after dermal filler injections in people with dark skin (Fitzpatrick Type IV-VI).
9. Patients with unattainable expectations are not suitable candidates for treatment.
10. If laser treatment, chemical peeling or any other procedure based on active dermal response is considered after treatment with Restylane Defyne, there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if Restylane Defyne is administered before the skin has healed completely after such a procedure. It is recommended that a period of 2 to 4 weeks elapses before applying different treatment modalities or until the skin has healed completely.
11. Patients should avoid excessive sun, UV lamp exposure, extreme temperatures, skin massage of the treatment area or face mask at least until any initial swelling and redness have resolved.
12. The safety for use during pregnancy, in breastfeeding females or in patients under 18 years has not been established.
13. Special caution should be exercised in treating patients with a tendency to form hypertrophic scars or any other healing disorders.
14. Please keep the traceability information and instruct the patients to identify genuine products.
15. Considerations should be given to the total dose of lidocaine administered if dental block or topical administration of lidocaine is used concurrently. High doses of lidocaine (more than 400mg) can cause acute toxic reactions manifesting as symptoms affecting the central nervous system and cardiac conduction.
16. Lidocaine should be used with caution in patients receiving other local anaesthetics or agents structurally related to amide-type local anaesthetics e.g., certain anti-arrhythmics, since the systemic toxic effects can be additive.
17. Lidocaine should be used with caution in patients with epilepsy, impaired cardiac conduction, severely impaired hepatic function or severe renal dysfunction.
18. Individual variation and treatment area may affect the degradation of this product, in rare cases product remnants have been detected in tissue when the clinical effect has returned to baseline.

Potential complications and side effects

Anticipated injection-related reactions
After the injection, injection-related reactions are to be expected, such as erythema, swelling, pain, itching, bruising or tenderness at the implant site. Generally, these reactions resolve spontaneously within one to two weeks after injection.

Post marketing adverse event reporting
The following post marketing adverse events have been reported from worldwide sources after treatment with Restylane Defyne (non-exhaustive list). The frequency of reporting is based on the number of estimated treatments performed with the products.

1/1 000 – 1/10 000	Swelling/oedema with immediate onset and onset up to several weeks after treatment, Mass/induration.
1/10 000 – 1/100 000	Papules/nodules, Erythema, Pain/tenderness, Device ineffective, Infection/abscess including pustule, cellulitis and purulent discharge, Bruising/bleeding, Inflammation, Discolouration, Other injection site reactions and skin reactions including burning sensation, exfoliation, irritation, discomfort, dryness and warmth, Ischemia/necrosis including livedo reticularis, pallor and vascular occlusion, Granuloma/foreign body reaction, Pruritus, Hypersensitivity/angioedema, Eye disorders including eye contusion, eye irritation, eye pain, eye swelling, eyelid ptosis, and visual impairment such as blurred vision, Device dislocation, Neurological symptoms including facial paralysis, hypoaesthesia and paraesthesia, Rash.
<1/100 000	Scar/skin atrophy, Blisters/vesicles, Reactivation of herpes infection, Deformity/asymmetry, Capillary disorders such as telangiectasia, Dermatitis, Discharge, Urticaria, Acne, Extrusion of device, Non-dermatological events including chills, cutaneous contour deformity, dizziness, headache, malaise, nausea, pyrexia and vomiting, Other dermatological events such as skin pain.

Vascular compromise may occur due to an inadvertent intravascular injection or as a result of vascular compression associated with implantation of any injectable product. This may manifest as blanching, discolouration, necrosis or ulceration at the implant site or in the area supplied by the blood vessels affected; or rarely as ischemic events in other organs due to embolisation. Rare but serious cases of ischemic events associated with temporary or permanent vision impairment, blindness, cerebral ischemia or stroke have been reported following facial aesthetic treatments.

Symptoms of inflammation at the implant site commencing either shortly after injection or after a delay of up to several weeks have been reported. In case of unexplained inflammatory reactions infections should be excluded and treated if necessary since inadequately treated infections may progress into complications such as abscess formation. Treatment using only oral corticosteroids without concurrent antibiotic treatment is not recommended.

The prolonged use of any medication, e.g., corticosteroids or antibiotics in treatment of adverse events has to be carefully assessed, since this may carry a risk for the patient. In case of persistent or recurrent inflammatory symptoms, consider removal of the product by aspiration/drainage, extrusion or enzymatic degradation (use of hyaluronidase has been described in scientific publications). Before any removal procedure is performed, the swelling may be reduced by using, e.g., NSAID for 2-7 days or a short course of corticosteroids for less than 7 days, in order to more easily palpate any remaining product.

For patients who have experienced clinically significant reactions, a decision for retreatment should take into consideration the cause and significance of previous reactions.

Adverse events must be reported to Q-Med International Trading (Shanghai) Co., Ltd., the after sales service agent of Q-Med AB.

Assembly of needle to syringe
It is important to use a sterile, appropriate needle. Suitable needles (27G x ½" ultra thin wall) are supplied with the syringe in the blister pack.
Use surgical gloves, remove the cap from the needle and unscrew the tip cap from the syringe. Hold firmly around the syringe barrel and grasp the needle shield with the other hand. Screw the needle tight onto the syringe by simultaneously pushing and rotating firmly until the needle is completely locked. To ensure proper assembly, minimize the gap between the needle shield and the syringe. See Figure 1.
Remove the needle shield just before injection by pulling it straight out. Do not rotate.

Note! Improper assembly may cause leakage or needle disconnection.

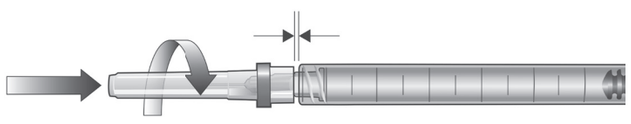

Figure 1

Treatment Procedure
The doctors have to inform the patients about the indications, expected result and duration of filler effect, contraindications, precautions, warnings and potential adverse events before treatment. Doctors shall also 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.

For initial injections, it is recommended not to use more than 1.5 mL for each nasolabial fold. The time interval between the initial injection and subsequent touch up injection in the treatment of nasolabial folds is at least 2 weeks. For touch-up injections, it is recommended not to use more than 0.5 mL for each nasolabial fold.

Cleanse the area to be treated with an antiseptic and allow it to dry before injection.

To avoid breakage of the needle, do not attempt to bend or otherwise manipulate it before or during treatment. If the needle gets bent, discard it and complete the procedure with a replacement needle of the same size. The size and the length of the needle will affect the force needed to extrude the gel. If a thinner and/or longer needle is used the resistance during injection may be too high resulting in an increased risk for leakage or separation of the needle and syringe

Before injecting the product, depress the plunger rod carefully until a small droplet is visible at the tip of the needle. Align the bevel of the needle by turning the syringe on its axis.

Aspiration is recommended prior to injection in order to reduce the risk of inadvertent injection into a blood vessel. Inject slowly in small aliquots.

Inject the gel by gently pressing down on the plunger rod with the thumb or palm of the hand.
Choose from a variety of injection techniques, i.e. serial puncture, linear threading or cross-hatching.

Do not apply excessive pressure to the syringe at any time. Presence of scar tissue may impede advancement of the needle. If resistance is encountered the needle should be partially withdrawn and repositioned or fully withdrawn and checked for function.
It is recommended to change needle for each new treatment site.

Only correct to the desired volume effect, at each treatment session. Do not overcorrect.

Markedly indurated defects may be difficult to correct. 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.

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.

Gently massage the treated area after injection.

If the treated area is swollen directly after the injection, an ice pack with adequate protective cloth can be applied on the site for a short period. Ice should be used with caution if the area is still numb from anesthetic to avoid thermal injury.

Additional implantations of Restylane Defyne may be necessary to achieve the desired level of correction if patients are not satisfied with the filler effect.

Note! The correct injection technique is important for the final result of the treatment. Please consult Q-Med International Trading (Shanghai) Co., Ltd., the after sales service agent of Q-Med AB, for more details about techniques and training opportunities.
The syringe, the needle and any gel that is unused and left in the syringe must be discarded immediately after the treatment session and must not be reused due to risk for contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.
Standard precautions apply when handling the needles. Needles should be disposed in a container dedicated for sharp devices.

Storage
Store up to 25° C. Protect from freezing and sunlight.

Date of manufacture
The date of manufacture is indicated on package.

Shelf life
The shelf life of the product is 24 months from the date of manufacture. Do not use after the expiry date indicated on package.

Others
For more information about the product, please consult Q-Med International Trading (Shanghai) Co., Ltd., the after sales service agent of Q-Med AB, or visit the website below:
www.restylane.com.cn

Restylane, 瑞蓝, Restylane Defyne, Defyne and Galderma are registered trademarks.

Symbols on Package

LOT	Lot Number
	Use by
	Date of manufacture
STERILE	Sterile. The contents of the syringe have been sterilized by using moist heat.
STERILE R	Sterilized using irradiation. The needles have been sterilized using irradiation.
REF	Catalogue number for the needle
	Manufacturer
2°C 25°C	Temperature limit
	Do not re-use.
	Caution, see instructions for use.
	Keep away from sunlight.
	Do not use if package is damaged.

Note! The product Restylane Defyne to be sold in China must be specially packed by the Swedish company Q-Med AB according to the requirement of National Medical Products Administration, P.R.China. Restylane Defyne must only be purchased through the sales channels of Q-Med AB.

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