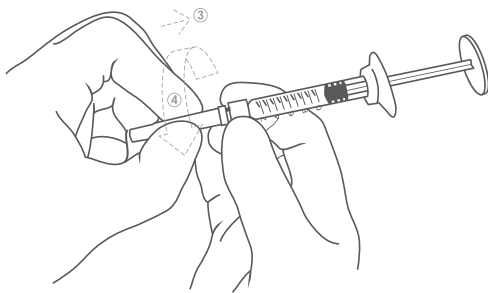
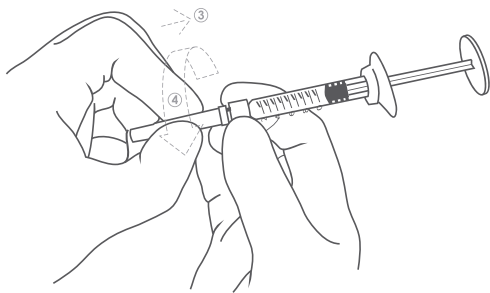
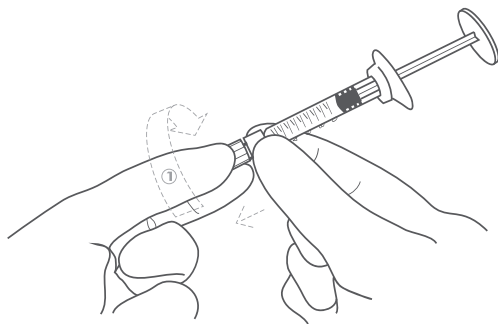
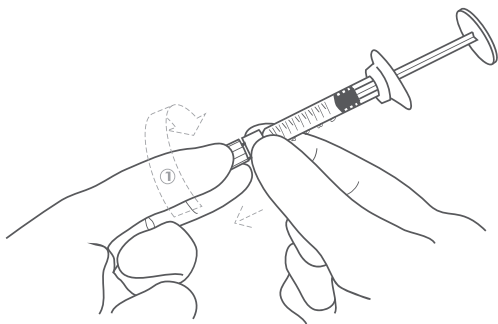

REVANESSE®
ULTRA™+

"普樂尼" 芮凡絲歐森玻尿酸植入物(含利多卡因)
"Prollenium" Revanesse Ultra+
衛部醫器輸字第038552號

使用前請務必詳閱原廠之使用說明書並遵照指示使用。



針頭組裝至針筒(1 mL)

1. 小心轉下針筒尾端的蓋子。
2. 緊握住針套的較寬部分。
3. 壓下並旋轉針套90°(旋轉四分之一圈)。這四分之一圈的旋轉是將針頭鎖上針筒的必要步驟。然後移除針套。
4. 用拇指和食指, 牢牢固定玻璃針筒和 Luer-lock 接頭。
5. 用另一手抓住針套。為了正確組裝, 請確實地推進並旋轉。

ASSEMBLY OF NEEDLE TO SYRINGE (1mL):

1. Carefully unscrew the glass syringe end cap.
2. Firmly grip the wider part of the socket.
3. Press down and rotate the socket 90° (a quarter turn) to lock the needle into the barrel. Then, remove the needle socket.
4. Firmly grip the glass syringe Luer-lock with thumb and forefinger to securely fasten the glass syringe and Luer-lock fittings.
5. Grasp the needle socket with your other hand. For proper assembly, press and rotate firmly.

針頭組裝至針筒(1.2 mL)

1. 取下針頭保護蓋, 並轉下玻璃針筒尾端的蓋子。
2. 用拇指和食指牢牢握住玻璃針筒的 Luer-lock 接頭。
3. 將針頭對準玻璃針筒的 Luer-lock 接頭。
4. 握穩玻璃針筒, 將針頭旋轉至緊固位置。
5. 注射前立即透過向前拉動的方式(請勿旋轉)取下針頭保護蓋。

ASSEMBLY OF NEEDLE TO SYRINGE (1.2mL):

1. Remove needle guard cap and unscrew the glass syringe end cap.
2. Firmly grip the glass syringe Luer-lock with thumb and forefinger.
3. Align the needle to the glass syringe Luer-lock.
4. Hold the glass syringe still and rotate the needle until it is tightly affixed.
5. Immediately prior to injection, remove needle guard by pulling forward (do not rotate).

成分

交聯型玻尿酸(高黏性).....25 mg/mL
利多卡因.....3% w/w

在磷酸鹽緩衝生理食鹽水中

[以丁二氧二氮丁基醚(BDDE, Butandiol-diglycidylether)進行交聯]

產品敘述

本產品為無色、無味、透明且水性的合成凝膠，放置在預先填充的一次性針筒中。本產品每盒包含兩支 1 mL 或 1.2 mL 的針筒，以及每盒一支或兩支 27 G 無菌針頭(型號: PRC-270131/HPC-270131)。

適應症

本產品為交聯型玻尿酸，藉由注入皮膚治療細部皺紋與凹陷部位之軟組織填補。植入有效期決於注射的深度及位置，約為6至12個月。

注射部位:法令紋(效期6-12個月)、嘴唇和口周細紋(效期6個月)

注射深度:中至深層真皮層(法令紋)，黏膜下層(嘴唇)和淺至中層真皮層(口周細紋)

注射劑量:每次治療單側法令紋最大劑量為2.0 mL。

每次治療單片嘴唇最大劑量為1.5 mL(上唇1.5 mL, 下唇1.5 mL)，口周細紋最大劑量為1.0 mL，因此單次療程可使用最大劑量為4.0 mL。

預期副作用

醫師必須告知患者每次注射本產品後皆有可能延遲或立即發生的潛在副作用。包含但不限於:

- 與注射相關的反應，例如注射部位暫時性紅斑、腫脹、疼痛、癢、變色或瘀傷。這些反應可能持續一週。

- 注射部位也可能會有結節或硬塊。

- 不正確的注射技術會造成產品功能不佳。

- 間隔環狀、腫脹形成、肉芽腫與過敏曾被回報與注射玻尿酸產品有關。醫師必須做個案病情形將這些反應納入考量。

被認為是過敏反應的情況在每1500次治療中少於一例。這些反應包括注射部位持續性紅斑、腫脹和硬塊。

這些輕度或中度反應可能在注射後不久或延遲2-4週後出現，平均會持續2週。通常這種反應具有自限性，會隨著時間過去而自癒。然而，有過敏反應的患者應立即聯繫醫師進行評估。有多種過敏的患者不應接受本產品治療。

禁忌症

- 本產品含利多卡因，對此物質有過敏史的患者不得使用。

- 請勿將本產品注入眼周(眼周或眼袋)。

- 請勿將本產品用於懷孕或哺乳的婦女。

- 本產品僅限用於注射使用，不得注入血管。可能會造成阻塞並導致血栓。

- 請勿將本產品用於會產生肥厚性疤痕的患者。

- 本產品含有微量的革蘭氏陽性菌蛋白，請勿用於曾對此物質過敏的患者。

- 請勿將本產品與雷射、脈衝光、化學換膚或磨皮治療一起使用。注射本產品前，醫事人員應確認皮膚狀況沉穩雷射、脈衝光、化學換膚或磨皮治療手術後已完成癒合。

- 請勿用於小於18歲的患者。

- 請勿用於皮膚有瘡瘍及/或其它炎性疾病的患者。

- 具有不切實際期望的患者。

- 具有自體免疫疾病或使用免疫療法患者。

- 有多種嚴重過敏症的患者。

- 注射部位附近有急性或慢性皮膚病的患者。

- 凝血障礙或使用抗凝血治療的患者。

- 對玻尿酸過敏的患者。

- 玻尿酸植入物禁止於全身麻醉下使用。

若出現持續一週以上的不良炎症反應，患者必須立即告知醫師。此情形應根據適當的處置進行治療(例如:使用皮質類固醇或抗生素)。所有其它的不良反應應請回報授權經銷商及/或製造業者。

使用與劑量

- 本產品應由經過培訓並掌握填補面部皺紋的正確注射技術的合格醫師進行注射。

- 治療前請先告知患者本產品的適應症、禁忌症與潛在的不良副作用。

- 欲治療的區域應經過徹底的消毒。請確保僅在無菌條件下進行注射。

- 請緩慢注射本產品，並僅施加最小的必要壓力。

- 本產品及針頭僅限單次使用。請勿重複使用。若重複使用，有感染或傳播血液疾病的風險。

- 注射前請讀本產品在室溫下至少30分鐘，未使用完應廢棄，不得冷藏重複使用。

- 若皮膚變白(蒼白)，請立即停止注射並按摩該部位直至回到正常膚色。

- 注射前，請壓下針筒的推桿直到針頭出現一小滴可見的液體。

注意事項

- 本產品不應被注入已有其它填充物的區域，目前沒有臨床資料能得知可能的反應。

- 請勿將本產品注入有永久性填充物或植入物的區域。

- 已知玻尿酸不相容於氯化苯二甲基胺等四級胺鹽。請確保本產品不會接觸到這些物質或有接觸過這些物質的醫療器材。

- 本產品不得用於隆乳，或植入骨頭、肌腱、韌帶及肌肉。

- 注射後12個小時內請避免接觸注射區域，並請避免長時間曝露於陽光、紫外線，以及極度的冷或熱。

- 直到最初的腫脹及泛紅消散前，請勿讓治療區域曝露於高溫(例如日光浴、日光燈等)或極端寒冷的環境。

- 若曾患有面部皰疹，注射針頭可能會增加再次發生皰疹的風險。

- 若治療前使用阿司匹林、非類固醇消炎藥物、聖約翰草或高劑量的維生素E補充劑，或任何類似藥物，包含注射部位的瘀斑和出血風險可能會因此增加。

- 根據利多卡因的毒理學風險評估，患者每年使用的劑量應限制於每60公斤體重20 mL。注射更高劑量的安全性尚未被確認。

- 用於小於18歲以及大於65歲患者的安全性尚未被確認。

- 有生病、細菌或病毒等感染、流感及發燒的患者，在症狀緩解前請勿使用本產品。

- 為了將潛在副作用的風險降至最低，本產品應由受過適當訓練、有經驗且了解注射部位周圍生理結構的醫事人員操作。

- 治療前可與患者討論軟組織注射的所有潛在副作用，以確保患者能對併發症及潛在不良反應的跡象保持警覺。

警告

請確保外盒上的密封未破損且產品的無菌未遭破壞。請確認產品未過期。本產品僅限單次使用，請勿重複使用。若重複使用則有感染或傳播血液疾病的風險。

- 若本產品進入血管可能會導致血栓、血管阻塞、缺血或梗塞。

- 與軟組織植入物注入臉部血管有關的罕見但嚴重副作用包括暫時或永久的視覺受損、眼痛、腦缺血或出血、導致失明、皮膚壞死，以及對臉部的皮下組織造成傷害。

- 若患者出現下列任何症狀，請立即停止注射，包括視覺改變、中風跡象、皮膚發白、或術中或術後立即有異常的疼痛。

- 若發生靜脈注射，患者應立即接受醫療照護，並可能需要由適當的醫事人員進行評估。

- 可能導致鼻淚管阻塞。

請勿將本產品用於血管密集的區域。用於眉間或鼻子周圍等血管密集區域會導致血管栓塞及眼部血管阻塞等症狀(例如失明)。

架保期與儲存

本產品的保存期限標示於包裝上。請存放於溫度介於2°-25°C的環境，並避免陽光直射及冷凍。

注意:為了確保治療成功與患者的舒適，請使用正確的注射技術。本產品僅限於符合當地法規與規範的醫事人員操作。

針筒上的刻度並不精確，僅供參考使用，請依臨床判斷控制注射劑量，勿僅依刻度作為劑量依據。注射的材料量最好由使用者的視覺和觸覺評估來確定。

製造業者

製造業者名稱: Prollem Medical Technologies Inc.

製造業者地址: 138 Industrial Parkway N., Aurora, Ontario, L4G 4C3, Canada

醫療器材商名稱: 埃默高有限公司

醫療器材商地址: 231 新北市新店區北新路3段221號10樓

COMPOSITION

Cross-linked hyaluronic acid.....	25mg/ml
Lidocaine.....	0.3% w/w
In phosphate buffered saline	
(Cross linked with Butandiol-diglycidylether (BDDE))	

DESCRIPTION

Revasense® Ultra™+ is a colorless, odorless, transparent and aqueous gel of synthetic origin. The gel is stored in a pre-filled disposable syringe. Each box contains two 1.0mL or 1.2mL syringes of Revasense® Ultra™+ along with one of two sterilized ZFG needles (model: PRC-270131 / HPC-270131).

APPLICATION RANGE / INDICATIONS

Revasense® Ultra™+ is a cross linked hyaluronic acid gel that is indicated for injection into the skin to treat fine lines and soft tissue filling in sunken areas of the face. Implantation life is dependent on depth and location of injection, which is about 6-12 months.

Injection site: nasolabial folds (valid for 6-12 months), fine lines around the lips and mouth (valid for 6 months)
Injection depth: medium to deep dermis (nasolabial folds), submucosal layer (lips), and shallow to middle dermis (thin perioral layer Pattern)

Injection dose: The maximum dose for each treatment of unilateral nasolabial folds is 2.0mL. The maximum dose for a single lip per treatment is 1.5mL (1.5 mL for upper lip, 1.5 mL for lower lip). The maximum dose for peripheral fine lines is 1.0mL, so the maximum dose that can be used in a single session is 4.0mL.

ANTICIPATED SIDE EFFECTS

Physicians must inform patients that with every injection of Revasense® Ultra™+ there are potential adverse reactions that may be delayed or occur immediately after the injection. These include but are not limited to:

- Injection-related reactions might occur, such as transient erythema, swelling, pain, itching, discoloration or tenderness at the injection site. These reactions may last for one week.
- Nodules or induration are also possible at the injection site.
- Poor product performance due to improper injection technique.
- Glabellar necrosis, abscess formation, granulomas and hypersensitivity have all been reported with injections of hyaluronic acid products. It is important for physicians to take these reactions into account on a case by case basis.

Reactions thought to be of hypersensitivity in nature have been reported in less than one in every 1500 treatments. These have consisted of prolonged erythema, swelling and induration at the implant site.

These reactions have started either shortly after injection or after a delay of 2-4 weeks and have been described as mild or moderate, with an average duration of 2 weeks. Typically, this reaction is self-limiting and resolves spontaneously with time. However, it is imperative that patients with hypersensitivity type reactions contact their physician immediately for assessment. Patients with multiple allergic reactions should be excluded from the treatment.

CONTRAINDICATIONS

- Contains lidocaine and is contraindicated for patients with a history of allergies to such material.
- Do not inject Revasense® Ultra™+ into eye contours (into the eye circle or eyelids).
- Pregnant women, or women during lactation should not be treated with Revasense® Ultra™+.
- Revasense® Ultra™+ is only intended for intradermal use and must not be injected into blood vessels. This may occlude and could cause an embolism.
- Patients who develop hypertrophic scarring should not be treated with Revasense® Ultra™+.
- Contains trace amounts of gram positive bacterial proteins, and is contraindicated for patients with a history of allergies to such material.
- Never use Revasense® Ultra™+ in conjunction with a laser, intense pulsed light, chemical peeling or dermabrasion treatments.
- People under the age of 18 should not be treated with Revasense® Ultra™+.
- Patients with acne and / or other inflammatory diseases of the skin should not be treated with Revasense® Ultra™+.
- Patients with unattainable expectations.
- Patients with auto-immune disorders or under immunotherapy.
- Patients with multiple severe allergies.
- Patients with acute or chronic skin disease in or near the injection sites.
- Coagulation defects or under anti-coagulation therapy.
- Patients with sensitivity to hyaluronic acid.
- Hyaluronic acid implants are prohibited for use while under general anesthesia.

It is imperative that patients with adverse inflammatory reactions that persist for more than one week report this immediately to their physician. These conditions should be treated as appropriate (i.e. corticosteroids or antibiotics). All other types of adverse reactions should be reported directly to the authorized distributor of the Revasense® family of products and / or to ProLium Medical Technologies Inc. directly.

ADMINISTRATION & DOSAGE

- Revasense® Ultra™+ should only be injected by or under the direct supervision of qualified physicians who have been trained on the proper injection technique for filling facial wrinkles.
- Before patients are treated they should be informed of the indications of the device as well as its contraindications and potential undesirable side effects.
- The area to be treated must be thoroughly disinfected. Be sure to inject only under sterile conditions.
- Inject the product slowly and apply the least amount of pressure necessary.
- Revasense® Ultra™+ and needles packaged with it are for single use only. Do not re-use. If re-used, there is a risk of infection or transmission of blood born diseases.

- Keep the product at room temperature for 30 minutes prior to injection.
- If the skin turns a whiteloor (blanching), the injection should be stopped immediately and the area should be massaged until the skin returns to its normal color.
- Before injecting, press on the plunger of the syringe until a small drop is visible at the tip of the needle.

PRECAUTIONS

- Revasense® Ultra™+ should not be injected into an area that already contains another filler product as there is no available clinical data on possible reactions.
- Revasense® Ultra™+ should not be injected into an area where there is a permanent filler or implant.
- Hyaluronic acid products have a known incompatibility with quaternary ammonium salts such as benzalkonium chloride. Please ensure that Revasense® Ultra™+ never comes into contact with this substance or medical instrumentation that has come into contact with this substance.
- Revasense® Ultra™+ should never be used for breast enlargement, or for implantation into bone, tendon, ligament or muscle.
- Avoid touching the treated area for 12 hours after injection and avoid prolonged exposure to sunlight, UV, as well as extreme cold and heat.
- Until the initial swelling and redness have resolved, do not expose the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold.
- If you have previously suffered from facial cold sores, there is a risk that the needle punctures could contribute to another eruption of cold sores.
- If you are using aspirin, non-steroidal anti-inflammatory medications, St. John's Wort or High doses of Vitamin E supplements prior to treatment or any similar medications be aware that these may increase bruising and bleeding at the injection site.
- Based on a toxicological risk assessment for lidocaine, patients should be limited to 20 mL per 60 kg (130 lbs) body mass per annum. The safety of injecting greater amounts has not been established.
- The safety for use in patients under 18 years or over 65 years has not been established.
- Patients who are visibly ill, with bacterial or viral infections, influenza, or active fever should not be treated until a resolution of their symptoms.
- In order to minimize the risk of potential complications, this product should only be used by health care practitioners who have appropriate training, experience, and who are knowledgeable about the anatomy at and around the site of injection.
- Health care practitioners 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.

WARNINGS

Confirm that the seal on the box has not been broken and sterility has not been compromised. Confirm that the product has not expired. Product is for single use only; do not re-use. If re-used, there is a risk of infection or transmission of blood born diseases.

- Introduction of product into the vasculature may lead to embolization, occlusion of the vessels, ischemia, or infarction.
- 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 practitioner specialist should an intravascular injection occur.
- May cause blockage of the nasolabial ducts.

The Revasense® family of products should not be used in areas that have high vascularity. Use in these areas such as the glabella and nose region has resulted in cases of vascular embolization and symptoms consistent with ocular vessel occlusion (i.e.: blindness).

SHELF LIFE & STORAGE

Expiry is indicated on each individual package. Store between 2°-25°C, and protect from direct sun light and freezing. **NOTE:** The correct injection technique is crucial to treatment success & patient satisfaction. Revasense® Ultra™+ should only be injected by a practitioner qualified according to local laws and standards.

The graduation on the syringe is not precise and should be used as a guide only. The amount of material to be injected is best determined by visual and tactile assessment by the user.

MANUFACTURER

Manufacturer Name: ProLium Medical Technologies, Inc.
 Manufacturer Address: 138 Industrial Parkway N., Aurora, Ontario, L4G 4C3, Canada
 License Holder's Name: Emergo Taiwan Limited
 License Holder's Address: 10F., No.221, Sec. 3, Beixin Rd., Xindian Dist., New Taipei City 231, Taiwan

象徵 | SYMBOL:



使用濕熱對注射器流體路徑進行消毒
Syringe fluid path sterilized using moist heat



採用輻照滅菌
Sterilized using irradiation



注射器
SYRINGE



針
NEEDLE



使用產品前請閱讀說明
Read the instructions before using the product



如果包裝已損壞, 請勿使用
Do not use if the package has been damaged



請勿重複使用
Do not reuse



遠離陽光
Keep away from sunlight



保持乾燥
Keep dry



儲存於 2 至 25 °C 之間
Store between 2 and 25°C



截止日期
Expiration date



批號
Lot number



製造商
Manufacturer



生產日期
Date of Manufacture

PROLLENIUM[®]
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PN13884 REV00