med supply
SOLUTIONS

PERFECTHA® SUBSKIN
Product Specifications

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CONTENTS OF THE CARTON

- 3 x 1ml single-use syringes containing cross-linked hyaluronic acid gel at a concentration of 20mg/ml in phosphate-buffered saline. The contents of the syringe have been steam-sterilised (CE 2195).
- 6 single-use 25G x 13mm needles, sterilised by radiation (CE 0123)*.
- 3 two-part tracking label(s) for the patient and for the healthcare professional (to be attached to the patient's records)

INTENDED USE

PERFECTHA is a line of resorbable hyaluronic acid (HA) gel implants intended for reconstructive purposes in the treatment, for instance, of facial lipoatrophy, or morphological asymmetry associated with the aging process or other underlying conditions. PERFECTHA is for intradermal and subcutaneous application and is implanted in the areas of the face and hands to fill skin depressions and also for the augmentation of tissue volume.

PERFECTHA SUBSKIN is an injectable implant for deep subcutaneous to supraperiosteal injection. It is indicated for significant loss of volume in areas such as cheekbones, chin, jawline, temples, forehead, bridge of the nose and hands.

PRODUCT DESCRIPTION

The device is intended to be used by registered healthcare professionals and intended to be used in adult patients (over 18) whom are not pregnant or breast-feeding and are deemed appropriate for treatment by the healthcare professional.

PERFECTHA SUBSKIN is a sterile cross-linked hyaluronic acid gel of non-animal origin. The gel is supplied in a pre-filled, ready-to-use, single-use syringe.

With PERFECTHA implants, it is possible to fill lines and restore volume to the face via the action of hyaluronic acid, which has the ability to bind to water. These are "passive" products, the main effect of which is achieved without any biological or pharmacological action. Their filling effect is a function of the quantity of implant injected; the maximum recommended dose must however not be exceeded. Effects are immediately apparent; how long they last depends on the volume and depth of injection, the healthcare professional's injection technique and the patient's lifestyle. PERFECTHA SUBSKIN is biodegradable and is broken down by the metabolic pathways of hyaluronic acid already present in the body. PERFECTHA is an implantable dermal filler. Treatment effects have variable duration** dependant on the product variant used, medical practitioner injection technique, patient lifestyle and metabolic rate.

**studies have shown effects from 6-18 months dependant on product variant.

Before the first session, contact your local Sinclair representative or authorised PERFECTHA distributor for additional information on injection techniques and training opportunities.

PRECAUTIONS FOR USE

- This product may be administered only by a registered healthcare professional in accordance with local regulations.
- This device is designed to be injected into the subcutaneous and supraperiosteal tissues by a healthcare professional who has been specifically trained in injection techniques for restoring volume to the face and hands. The healthcare professional’s technical competence is crucial to the success of the treatment.
- Take extra care in the treatment of anatomical regions in which there is an abundance of blood vessels and/or nerve fibres.
- All injections carry a risk of infection, aseptic techniques and standard practices should be employed to avoid contamination and infection.
- Knowledge of the anatomy of the site to be treated and specific precautions are essential in order to avoid perforation or compression of vessels, nerves and other more fragile structures.
- Use of the supplied needle is recommended. The design, diameter and length have been validated for optimum use with the injection.

- It is also possible to use injection accessories presented in the table on the back page of this leaflet. The maximum recommended lengths of needles and cannulas covering a range of gauge sizes are included. The design, diameter and length have been validated for effective use with the injection. (***The needle information in the table is not applicable to Terumo regular walled needles, which are not recommended for use with PERFECTHA products).
- The needle and cannula recommendations are based solely on extrusion testing and clinical judgement should be used to determine the gauge and length most suitable for the application area/depth of treatment.
- Use of injection equipment other than that recommended in the table of alternatives increases the risk of the accessory and/or the Luer lock fitting becoming detached.
- There is known incompatibility between hyaluronic acid and quaternary ammonium salts such as benzalkonium chloride (precipitation of hyaluronic acid). Therefore PERFECTHA SUBSKIN should never come into contact with such products or with medical or surgical equipment treated with this type of product. The healthcare professional should check the composition of the disinfectant used to clean the patient's skin prior to the injection and exclude the use of products containing such substances.
- Avoid injection in patients with clotting disorders or taking thrombolytics, anticoagulants, aspirin, non-steroidal anti-inflammatory drugs or vitamin C. These can predispose to swelling reactions at the injection site and can increase bleeding and the risk of bruising after the injection. These substances should be temporarily discontinued at least 7 to 10 days before the injection, and only with medical clearance with prescribed anticoagulants such as warfarin or clopidogrel bisulfate.
- The maximum recommended dose of PERFECTHA SUBSKIN gel is no more than 30ml per 60kg bodyweight per full course of treatment without prior anaesthesia, and should not exceed 60ml per 60kg bodyweight per year.
- The patient should be advised not to apply make-up for 24 hours following the injection and to avoid prolonged exposure to UV rays, temperatures below 0°C, saunas and Turkish baths for 2 to 3 weeks following the injection.
- Take extra care when injecting into the nose as this is a high risk, sensitive area more prone to developing adverse events.

CONTRAINDICATIONS

- Do not mix with other products before injection. This can alter the functionality of the product and affect the sterility of the gel leading to an increased risk of infection.
- Do not inject into the periorbital region (eyelids, under-eye dark circles, crow's feet, tear trough) or glabella region as there is risk of ocular ischaemic events leading to loss of vision.
- Do not inject via the intramuscular or intravascular route. Risk of vascular compression events, which can manifest as discolouration, necrosis or ulceration at the implant site or in the area supplied by the affected blood vessels; risk of ischaemic events in other organs as a result of embolism. In the event of superficial discolouration or blanching of the skin, the injection must be stopped immediately and the area massaged until its normal colour is restored.
- Do not over-correct.
- Avoid injections in patients with known hypersensitivities to avian proteins, feathers and egg products, as patients with known hypersensitivities to these items may also be sensitive to sodium hyaluronate.
- Do not use in patients:
    - with epilepsy which is not controlled by treatment
    - with tendency to develop hypertrophic scars
    - with known hypersensitivity to hyaluronic acid
    - with porphyria
    - with active (or a history of) autoimmune disease
    - with a history of streptococcal disease (recurrent throat infections, acute rheumatic fever with or without cardiac involvement)
    - with areas affected by inflammatory and/or infectious skin problems (acne, herpes etc.)

or tumours at or near the treatment site
    - undergoing laser or UV treatment, deep chemical peel, dermabrasion or prolonged sun exposure. Following a superficial peel, injection is not recommended if the inflammatory reaction induced by the peel is significant and/or still visible
    - receiving medical treatment that reduces or inhibits liver metabolism (cimetidine, beta blockers)
    - that are pregnant or breastfeeding women, children
- Do not use on areas previously treated with fillers of animal origin, permanent implants or implants containing a substance other than hyaluronic acid. Risk of incompatibility between products; risk of activation or reactivation of the immune system and/or latent infections.
- When injecting into the hand do not use when there is joint, tendon, or vascular disease affecting the hand to be treated.

INSTRUCTIONS FOR USE

1. Before starting treatment, the healthcare professional must obtain information about the patient's history and state of health. The healthcare professional must examine the compatibility of the patient, the chosen treatment and the anatomical area to be treated; in particular, it is recommended that double testing or preventive treatment are offered before any injection. The healthcare professional must adhere strictly to the conditions of use for which the device is intended. The healthcare professional must inform the patient about the indications, contraindications, incompatibilities, side effects and undesirable effects of the device.
2. Assemble the Syringe ready for injection:
    a. Holding the syringe upright on the ribbed part of the Luer lock, tilt the white cap to break seals (Fig 1).
    b. Remove the syringe cap in a straight upward direction (Fig 2).
    c. Unscrew cap from the needle/ cannula casing. Holding the Luer Lock firmly in a fixed position, screw the desired needle/ cannula into the Luer lock of the syringe by rotating the needle/ cannula (Fig 3).
    d. Remove needle/ cannula casing.
3. Before starting the injection, expel all the air from the needle/ cannula by pushing on the plunger until a drop of gel appears at the tip of the needle/ cannula.
4. The patient should be seated at an angle of at least 45° in order to prevent the face from becoming distorted, which increases the risk of "imprecise treatment".
5. Marking the area to be treated should help guarantee the precision of the injection. The area to be treated should first be cleaned and disinfected with an appropriate antiseptic solution. Local or regional anaesthetic block may be used depending on patient/ healthcare professional preference.
6. The quantity to be injected depends on the area to be corrected. Do not inject more than 3.0ml per treatment site during each session.
7. Inject the product slowly; injection of one 1ml syringe takes between 4 to 5 minutes.
   A low injection speed may help to prevent the detachment of accessories during injection and to reduce the occurrence of local adverse events after injection.
8. If the needle/ cannula becomes blocked, do not increase the pressure on the plunger rod; stop the injection and replace the needle/ cannula. A bubble in the syringe barrel does not constitute a known risk during administration.
9. Administration must be halted just before withdrawing the needle/ cannula in order to prevent spillage of the product at the administration site.
10. As the results are immediate, the quantity administered must correct the defect without producing over-correction.
11. The treated area should be massaged gently to ensure the implant is well distributed.
12. Application of ice packs to the treated area for several minutes is recommended in order to minimise swelling.
13. Dispose of syringe and needle/ cannula as contaminated clinical waste.

SIDE EFFECTS

- Accidental injection into terminal vessels or vascular compression caused by implantation of an injectable product may lead to vascular occlusion, with consequences such as ischaemia/necrosis.
- Damage to blood vessels may cause significant bruising and, in the most severe cases, lead to varicose veins.
- Involvement of nerves may cause persistent pain, itching and, in the most severe cases, transient paraesthesia.
- Too deep an injection or intramuscular injection may result in increased consumption of hyaluronic acid and hence shorten the duration of effect of the implant.
- Too superficial an injection may cause colouration or discolouration of the area around the injection site and/or formation of palpable nodules.
- Failure to observe the rules of hygiene for injection and the manufacturer's warnings may lead to the development of an infection.
- There is a potential for an increased risk of post-inflammatory hyperpigmentation in people of darker skin colour.
- In rare cases, severe allergic reaction (anaphylactic shock) that requires immediate emergency medical assistance can occur.
- Migration/movement of filler material at injection site or through the skin could occur which may result in tissue reaction or infection.
- Undesirable immediate/delayed onset effects include (non-exhaustive list):
    - inflammatory reactions (redness, swelling, rash, oedema, erythema etc.)
    - bruising
    - itching
    - tenderness
    - induration/nodules/papules/lump/fistula/granuloma
    - discolouration
    - pain/tenderness
    - hypersensitivity
    - acne
    - atrophy/scarring
    - blisters
    - dermatitis
    - herpes reactivation
    - ecchymosis

Most symptoms usually resolve within 1 to 2 weeks after the injection. If these effects persist beyond 2 weeks or if any other side effects appear, the patient must tell his/her healthcare professional as soon as possible. The healthcare professional should manage these with appropriate treatment.

- Very rare reactions include (non-exhaustive list):
    - infection
    - neurological symptoms such as paraesthesia
    - abscess
    - implant migration
    - visual disturbance
    - ischaemia/necrosis
    - ocular ischaemia leading to vision loss

The onset of these undesirable effects or any other side effects must be reported immediately. Please contact the local Sinclair representative or authorised PERFECTHA distributor. Alternatively send the details to Sinclair on: quality@sinclairpharma.com

WARNINGS

- Do not freeze (<2°C) for risk of implant degradation.
- Check the integrity of the packaging, product and needles provided; do not use the device if the packaging is damaged or open.
- Check the expiry dates stated on the labelling; do not use the device if the expiry date has

passed.

- Do not re-sterilise as the product quality cannot be guaranteed following additional processing.
- Do not reuse: PERFECTHA SUBSKIN is for single use. The syringe, needle/ cannula used, and any remaining product must be discarded in suitable containers after use. The reuse of disposable single-use syringes and needles/ cannulas exposes the public to serious risks of infection. Reuse of any residual product can result in an increase in known undesirable effects.
- Never attempt to straighten a bent needle/ cannula; they must be discarded in suitable containers and replaced.

The expiry date of the product is stated on the packaging.
Store between 2°C and 30°C, protect from frost and sunlight.
If you have any complaints then please contact quality@sinclairpharma.com

Caution
Attention
Precaución
Upozornění
تنبيه
주의
警告
注意
ข้อควรระวัง
Thận trọng
Perhatian
Осторожно
Уага
Attenzione
Atenção
Sicherheitshinweis
Waarschuwing
Försiktighet
Advarsel
Προσοχή
Dikkat
Upozornenie
Внимание
Atenție
Oprez
Figyelem
Svarilo

Manufacturer
Fabricant
Responsable de la fabricación
Výrobce
المُصنِّع
제조업체
生产商
製造者
ผู้ผลิต
Nhà sản xuất
Produsen
Изготовитель
Виробник
Produttore
Fabricante
Hersteller
Fabrikant
Tillverkare
Producent
Παρασκευαστής
Üretici
Výrobca
Производител
Fabricantul
Proizvođač
Gyártó
Proizvajalec

Temperature Limit
Limites de température
Límite de temperatura
Teplotní meze
حد درجة الحرارة
온도 제한
应用温度范围
使用温度範囲
ขีดจำกัดอุณหภูมิ
Giới hạn Nhiệt độ
Batas Suhu
Температура хранения
Температура зберігання
Limite di temperatura
Limite de temperatura
Temperaturbegrenzung
Temperatuurgrens
Temperaturgräns
Temperaturgrænse
Όριο θερμοκρασίας
Sıcaklık Sınırı
Limit teploty
Температурна граница
Limita de temperatură
Temperaturno ograničenje
Hőmérsékleti korlátozás
Temperaturna omejitev

Do not resterilise
Ne par restériliser
No reesterilizar
Neresterilizujte
لا تُعيد تعقيمه
재멸균 금지
不可重新消毒
再滅菌禁止
ห้ามนำไปฆ่าเชื้อซ้ำ
Không tiệt trùng lại
Jangan disterilkan ulang
Не стерилизовать повторно
Не стерилізувати повторно
Non risterilizzare
Não voltar a esterilizar
Nicht erneut sterilisieren
Niet opnieuw steriliseren
Får inte omsteriliseras
Må ikke resteriliseres
Μην επαναποστειρώνετε
Yeniden sterilize etmeyin
Nesterilizujte opakovane
Да не се стерилизира повторно
A nu se resteriliza
Ne sterilizirati ponovno
Tilos újrasterilizálni
Ne sterilizirajte ponovno

Keep away from sunlight
Conserver à l'abri du soleil
Mantener lejos de la luz solar
Chraňte před působením slunečního záření
يُحفظ بعيدًا عن ضوء الشمس
직사광선 노출 금지
避免日光照射
日光の当たる場所に保管しないでください
เก็บให้ห่างจากแสงอาทิตย์
Tránh ánh nắng mặt trời
Jauhkan dari sinar matahari
Хранить вдали от воздействия солнечного света
Зберігати якнайдалі від прямих сонячних променів
Tenere lontano dalla luce solare
Manter afastado da luz solar
Vor Sonnenlicht schützen
Uit het zonlicht houden
Ljuskänsligt
Må ikke opbevares i sollys
Φυλάσσετε μακριά από το ηλιακό φως
Güneş ışığından uzak tutun
Chráňte pred slnečným žiarením
Да се пази от слънчева светлина
A se feri de lumina solară
Držite podalje od sunčeve svjetlosti
Napfénytől védve tárolandó
Zaščitite pred sončno svetlobo

Batch code
Numéro de lot
Código de lote
Kód šarže
كود التشغيلة
배치 코드
批号
バッチコード
รหัสแบตช์
Mã lô hàng
Kode batch
Код партии
Код партії
Codice lotto
Lote
Chargenbezeichnung
Partijcode
Sats
Batchkode
Κωδικός παρτίδας
Parti Kodu
Kód šarže
Код на партидата
Codul lotului
Serijski broj
Tételkód
Oznaka serije

Date of Manufacture
Date de fabrication
Fecha de fabricación
Datum výroby
تاريخ التصنيع
제조 일자
生产日期
製造日
วันที่ผลิต
Ngày Sản xuất
Tanggal Pembuatan
Дата изготовления
Дата виробництва
Data di fabbricazione
Data de fabrico
Herstellungsdatum
Productiedatum
Tillverkningsdatum
Produktionsdato
Ημερομηνία παρασκευής
Üretim Tarihi
Dátum výroby
Дата на производство
Data fabricației
Datum proizvodnje
Gyártás dátuma
Datum izdelave

Sterilised using steam
Stérilisé à la vapeur
Esterilizado por vapor
Sterilizováno parou
مُعقَّم بالبُخار
증기 멸균
蒸汽灭菌
蒸気滅菌
ผ่านการฆ่าเชื้อด้วยไอน้ำ
Tiệt trùng bằng hơi nước
Disterilkan menggunakan uap
Стерилизация паром
Стерилізація парою
Sterilizzato in autoclave
Esterilizado a vapor
Steril mit Dampf
Gesteriliseerd met stoom
Steriliserad med ånga
Steriliseret med damp
Αποστειρωμένο με χρήση ατμού
Buhar ile sterilize edilmiştir
Sterilizované pomocou pary
Стерилизира се с помощта на пара
Sterilizat cu abur
Sterilizirano parom
Gőzzel sterilizálva
Sterilizirano s paro

Medical Device
Dispositif médical
Producto sanitario
Medicínský prostředek
جهاز طبيّ
의료 기기
医疗器械
医療器具
อุปกรณ์ทางการแพทย์
Thiết bị Y tế
Alat Kesehatan
Медицинское изделие
Медичний виріб
Dispositivo medico
Dispositivo médico
Medizinprodukt
Medisch hulpmiddel
Medicinteknisk produkt
Medicinsk udstyr
Ιατροτεχνολογικό προϊόν
Tıbbi Cihaz
Zdravotnícka pomôcka
Медицинско изделие
Dispozitiv medical
Medicinski proizvod
Orvosi eszköz
Medicinski pripomoček

Consult Instructions for Use
Consulter la notice d'utilisation
Consultar las instrucciones de uso
Viz návod k použití
راجع إرشادات الاستعمال
사용 설명서 참조
查阅使用说明书
使用方法を参照してください
ศึกษาวิธีใช้
Tham khảo Hướng dẫn Sử dụng
Baca Petunjuk Penggunaan
Обратитесь к инструкции по применению
Зверніться до інструкції із застосування
Consultare le istruzioni per l'uso
Consultar as Instruções de Utilização
Informationen beachten
Raadpleeg de instructies voor gebruik
Läs bruksanvisningen
Se brugsanvisningen
Συμβουλευτείτε τις οδηγίες χρήσης
Kullanma Talimatlarına Bakın
Pozrite si návod na používanie
Направете справка в Указанията за употреба
Consultați instrucțiunile de utilizare
Pogledati u uputama za uporabu
Olvassa el a használati útmutatót
Glejte navodila za uporabo

Use-by Date
Date limite d'utilisation
Fecha de caducidad
Datum spotřeby
التاريخ الذي يُستعمل قبله
사용 기한
有效期
使用期限
วันที่หมดอายุ
Sử dụng đến ngày
Gunakan hingga Tanggal
Срок годности
Термін придатності
Utilizzare entro
Utilizar até
Verfalldatum
Uiterste gebruiksdatum
Utgångsdatum
Anvendes før
Ημερομηνία λήξης
Son Kullanma Tarihi
Dátum spotreby
Използвайте до
Data expirării
Datum isteka uporabe
Felhasználhatóság dátuma
Datum izteka roka uporabnosti

Serial number
Numéro de série
Número de serie
Sériové číslo
الرقم المُتسلسل
일련번호
序列号
シリアル番号
หมายเลขผลิตภัณฑ์
Số sê-ri
Nomor seri
Серийный номер
Серійний номер
Numero di serie
Número de série
Seriennummer
Serienummer
Serienummer
Serienummer
Σειριακός αριθμός
Seri numarası
Sériové číslo
Сериен номер
Număr de serie
Serijski broj
Sorozatszám
Serijska številka

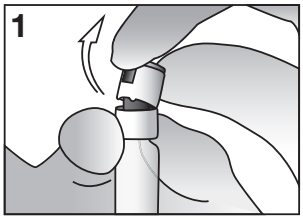
Sterilised using irradiation
Stérilisé par irradiation
Esterilizado por radiación
Sterilizováno ozářením
مُعقَّم بالإشعاع
방사선 멸균
辐照灭菌
放射線滅菌
ผ่านการฆ่าเชื้อด้วยการฉายรังสี
Tiệt trùng bằng chiếu xạ
Disterilkan menggunakan iradiasi
Радиационная стерилизация
Радіаційна стерилізація
Sterilizzato mediante irradiazione
Esterilizado por radiação
Steril durch Bestrahlung
Gesteriliseerd met straling
Steriliserad med strålning
Steriliseret med stråling
Αποστειρωμένο δια ακτινοβολίας
Işınlama ile sterilize edilmiştir
Sterilizované pomocou ožarovania
Стерилизира се с помощта на радиация
Sterilizat prin iradiere
Sterilizirano zračenjem
Besugárzással sterilizálva
Sterilizirano z obsevanjem

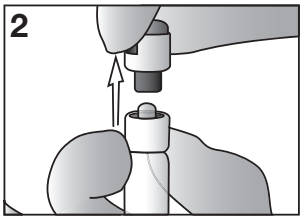
Do not re-use
Ne pas réutiliser
No reutilizar
Nepoužívejte opakovaně
لا تعيد استعماله
재사용 금지
不可重复使用
再使用禁止
ห้ามใช้ซ้ำ
Không tái sử dụng
Jangan gunakan kembali
Не использовать повторно
Не використовувати повторно
Non riutilizzare
Não reutilizar
Nicht zur Wiederverwendung
Niet hergebruiken
Får inte återanvändas
Må ikke genbruges
Μην επαναχρησιμοποιείτε
Yeniden Kullanmayın
Nepoužívajte opakovane
Да не се използва повторно
A nu se reutiliza
Ne koristite ponovno
Tilos újrafelhasználni
Samo za enkratno uporabo

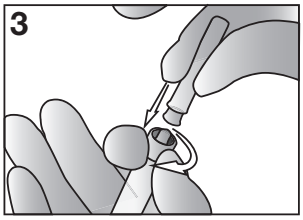
Do not use if package is damaged
Ne pas utiliser si l'emballage est endommagé
No utilizar si el envase está dañado
Nepoužívejte, je-li obal poškozený
لا تستعمل المنتج إذا كانت العبوة تالفة
포장이 손상된 경우 사용 금지
如包装损坏，不可使用
パッケージ破損の際は使用しないでください
ห้ามใช้หากบรรจุภัณฑ์เสียหาย
Không sử dụng nếu bao bì bị hỏng
Jangan gunakan jika kemasan rusak
Не использовать при повреждении упаковки
Не застосовувати в разі пошкодження упаковки
Non usare se la confezione è danneggiata
Não utilizar se a embalagem estiver danificada
Bei beschädigter Packung nicht verwenden
Niet gebruiken als de verpakking beschadigd is
Får inte användas om förpackningen är skadad
Må ikke bruges, hvis emballagen er beskadiget
Μη χρησιμοποιήσετε αν η συσκευασία έχει υποστεί ζημιά
Ambalajı hasarlı ise kullanmayın
Nepoužívajte, ak je obal poškodený
Не използвайте, ако опаковката е повредена
A nu se utiliza dacă ambalajul este deteriorat
Nemojte koristiti ako je pakiranje oštećeno
Ne használja fel, ha a csomagolás sérült
Ne uporabljajte, če je embalaža poškodovana

Ingredients	Quantity (w/w%)
Sodium Hyaluronate	2.0
Sodium Chloride	0.9
Sodium dihydrogen phosphate	0.0187
Disodium Phosphate	0.0374
Water for Injections	q.s to 100%

Gauge	Maximum Length
Needle* **	
21-22 G	50 mm
25 G	25 mm
27-30 G	13 mm
Cannula	
21-27G	50 mm







* For Needles:
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EC-Representative: Emergo Europe, Molenstraat 15, 2513 BH The Hague (NL)

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