med supply
SOLUTIONS

PERFECTHA® DERM Lidocaine Product Specifications

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CONTENTS OF THE CARTON

PERFECTHA FINELINES, **DERM** and **DEEP LIDOCAINE** 1 blister pack containing:

- 1 single-use syringe containing 1.0 ml cross-linked hyaluronic acid gel at a concentration of 20 mg/ml in phosphate-buffered saline and 0.3% (w/w) lidocaine hydrochloride (CE 2195)
- 2 sterile single use needles (CE 0123)*
    - 30G x 13mm for **PERFECTHA FINELINES LIDOCAINE** and **PERFECTHA DERM LIDOCAINE**
    - 27G x 13mm for **PERFECTHA DEEP LIDOCAINE**
- 1 two-part tracking label for the patient and for the healthcare professional (to be attached to the patient's records)

PERFECTHA SUBSKIN LIDOCAINE 3 blister packs each containing:

- 1 single-use syringe containing 1.0 ml cross-linked hyaluronic acid gel at a concentration of 20 mg/ml in phosphate-buffered saline and 0.3% (w/w) lidocaine hydrochloride (CE 2195)
- 2 sterile single use needles 25G x 13mm (CE 0123)*
- 1 two-part tracking label for the patient and for the healthcare professional (to be attached to the patient's records)

INTENDED USE

The **PERFECTHA LIDOCAINE** product range are resorbable hyaluronic acid (HA) with 0.3% (w/w) lidocaine hydrochloride 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 LIDOCAINE** 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. Lidocaine hydrochloride 0.3% (w/w) is integrated into the product to reduce the sensation of pain during treatment.

PERFECTHA FINELINES LIDOCAINE is an injectable implant for intradermal injection. It is indicated for the filling of superficial lines and depressions, such as periorbital and peribuccal fine lines. It is also indicated for use in the tear troughs by injection into the supraperiosteal plane.

PERFECTHA DERM LIDOCAINE is an injectable implant for superficial subcutaneous injection. It is indicated for the filling of medium lines and depressions, such as nasolabial folds and marionette lines, for lip enhancement and scars.

PERFECTHA DEEP LIDOCAINE is an injectable implant for subcutaneous injection. It is indicated for the filling of deep lines and depressions such as nasolabial folds and marionette lines. It is also indicated for moderate contouring and volumisation in areas such as cheekbones, chin, jawline, temples, nose, sub-orbicularis oculi fat (SOOF); and for lip augmentation.

PERFECTHA SUBSKIN LIDOCAINE 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 a registered healthcare professional 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 LIDOCAINE is a sterile cross-linked hyaluronic acid gel of non-animal origin with 0.3% (w/w) lidocaine hydrochloride. The gel is supplied in a pre-filled, ready-to-use, single-use syringe. Each carton contains single-use accessories to be used with the product supplied.

PERFECTHA LIDOCAINE is an implantable, resorbable dermal filler. The effects of **PERFECTHA LIDOCAINE** are immediately apparent; how long it lasts depends on the volume and depth of injection, the healthcare professional's injection technique and the patient's lifestyle. Treatment effects have variable duration** dependant on the product variant used, healthcare professional injection technique, patient lifestyle and metabolic rate.

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

Lidocaine hydrochloride 0.3% (w/w) is integrated into the gel to reduce the sensation of pain during treatment. With the lidocaine being integrated into the injectable implant an extra anaesthetic step is not required and makes the whole process much more pleasant for the patient.
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 by a healthcare professional who has been specifically trained in injection techniques for dermal filler procedures. 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.
- The healthcare professional must take into account the fact that this product contains lidocaine hydrochloride.
- 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 effective use with the injection.
- If using accessories other than those supplied, the maximum recommended lengths of needles and cannulas covering a range of gauge sizes are presented in the table at the end of this booklet (***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 supplied or mentioned 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 LIDOCAINE** should never come into contact with such products or with medical or surgical equipment treated with this type of product. The physician 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 after consulting with the patient’s healthcare professional.
- The maximum recommended dose of **PERFECTHA LIDOCAINE** gel is no more than 30 ml per 60 kg bodyweight per full course of treatment, and should not exceed 60 ml per 60 kg 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, and to extreme heat and cold e.g. temperatures below 0°C, saunas and Turkish baths for 2 to 3 weeks following the injection.
- Extra care is needed when injecting **PERFECTHA FINELINES LIDOCAINE** into the periorbital region (eyelids, under-eye dark circles, crow's feet, tear trough) or glabellar due to risk of ocular ischaemic events leading to loss of vision.
- Take extra care when injecting **PERFECTHA FINELINES LIDOCAINE** into the periorbital region, tear trough, nose or lips as these are high risk, sensitive areas more prone to

developing adverse events.

- Take extra care when injecting **PERFECTHA DERM** / **DEEP LIDOCAINE** into the nose or lips as these are high risk, sensitive areas more prone to developing adverse events.
- Take extra care when injecting **PERFECTHA SUBSKIN LIDOCAINE** 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 via the intramuscular or intravascular route, as there is 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 during treatment, 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 known hypersensitivity to lidocaine or to amide-type local anaesthetics
    - 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 could lead to risk of activation or reactivation of the immune system and/or latent infections.
- Do not inject **PERFECTHA DERM** / **DEEP** / **SUBSKIN LIDOCAINE** 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.
- When injecting **PERFECTHA SUBSKIN LIDOCAINE** 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, precautions for use, contraindications and possible side effects of the device.

2. Assemble the syringe ready for injection:
    a. Holding the syringe upright, pull tip cap off the syringe (Fig 1).
    b. Unscrew cap from the needle casing. Holding the Luer Lock firmly in a fixed position, screw the needle into the Luer lock of the syringe by rotating the needle (Fig 2).
    c. Remove needle 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. The use of **PERFECTHA LIDOCAINE** does not require additional anaesthesia.
6. The quantity to be injected depends on the area to be corrected. Do not inject more than 3.0 ml per treatment site during each session.
7. Inject the product slowly; injection of one 1.0 ml 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

- Toxic effects after administration of local anaesthetics are a result of excessively high plasma concentrations; severe toxicity usually results from inadvertent intravascular injection or too rapid injection.
- Toxic effects of the lidocaine hydrochloride can include; feeling of inebriation and light-headedness followed by drowsiness, numbness of the tongue and perioral region, restlessness, paraesthesia (including sensations of hot and cold), dizziness, blurred vision, tinnitus, headache, nausea and vomiting, muscle twitching, tremors and convulsions. Effects on the cardiovascular system include myocardial depression and peripheral vasodilation resulting in hypotension and bradycardia; arrhythmias and cardiac arrest can occur. In rare cases methemoglobinemia may occur.
- 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
    - haematoma
    - 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 physician as soon as possible. The physician 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 any side effects must be reported immediately. Please contact the local Sinclair representative or authorised **PERFECTHA** distributor. Alternatively send the details to Sinclair at 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 carton 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 LIDOCAINE** 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 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 light.
If you have any complaints then please contact quality@sinclairpharma.com

Caution

Manufacturer

Temperature Limit

Do not resterilise

Keep away from sunlight

Batch code

Date of Manufacture

Sterilised using steam

Medical Device

Consult Instructions for Use

Use-by Date

Serial number

Sterilised using irradiation

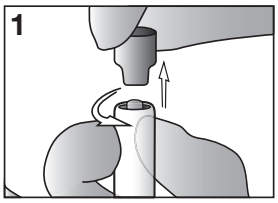
Do not re-use

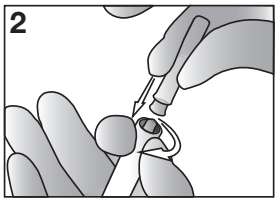
Do not use if package is damaged

PRODUCT COMPOSITION	
Ingredients	**Quantity (w/w%)**
Sodium Hyaluronate	2.0
Sodium Chloride	0.9
Lidocaine Hydrochloride	0.3
Sodium dihydrogen phosphate	0.019
Disodium Phosphate	0.037
Water for Injections	q.s to 100%

Gauge	Maximum Length
Needle* **	
FINELINES, DEEP, DERM, SUBSKIN LIDOCAINE	
21-22 G	50 mm
25 G	25 mm
27-30 G	13 mm
Cannula	
FINELINES, DEEP, DERM, SUBSKIN LIDOCAINE	
21-27G	50 mm
FINELINES LIDOCAINE	
30G	25mm

*For needles:
Legal Manufacturer – TSK Laboratory, Japan;
CE 0123
EC-Representative: Emergo Europe,
Molenstraat 15, 2513 BH The Hague (NL)





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