

INSTRUCTIONS FOR USE

Description

DERMA SECRET is a sterile, injectable, apyrogenic, resorbable medical device made with cross-linked hyaluronic acid derived from bacterial fermentation. DERMA SECRET is in the form of a homogeneous, transparent, colourless gel contained in a pre-filled, single-use, sterile syringe with Luer-lock fitting.

Composition

DERMA SECRET LIGHT: Concentrated cross-linked hyaluronic acid. Sterile saline solution: as needed. DERMA SECRET SOFT: Medium-concentration cross-linked hyaluronic acid. Sterile saline solution: as needed. DERMA SECRET STRONG: High-concentration cross-linked hyaluronic acid. Sterile saline solution: as needed. DERMA SECRET EXTRA STRONG: Extremely-concentrated cross-linked hyaluronic acid. Sterile saline solution: as needed. DERMA SECRET VOLUME: Concentrated cross-linked hyaluronic acid. Sterile saline solution: as needed. DERMA SECRET SUPER LIGHT: Low cross-linking concentrated hyaluronic acid. Sterile saline solution: as needed.

Action mechanism

The action of DERMA SECRET consists in increasing the volume of the dermal-epidermal tissue based on the natural ability of the hydrophilic molecules of hyaluronic acid to bond with a much greater quantity of water than their weight. This fills the intradermal spaces and integrates the intercellular matrix, making the tissues firm. The cross-linking of the hyaluronic acid contained in the product makes the filling effect more stable and longer lasting.

Directions for use

DERMA SECRET is intended for use as a temporary filler for the correction of skin defects such as wrinkles or scars. It is also recommended for pathological conditions such as lipodystrophy connected to infection from HIV and antiretroviral therapy. In particular we recommend the following use: DERMA SECRET LIGHT for the correction of superficial lines and wrinkles, from fine to medium. Particularly indicated for defects and areas: laugh lines, barcodes, periocular wrinkles, scar sequelae (acne, chicken pox). DERMA SECRET SOFT for the correction of medium-superficial wrinkles on the face. Particularly indicated for defects and areas: nasolabial wrinkles, nose, lips, frown lines. DERMA SECRET STRONG for the correction of deep facial wrinkles and folds. Particularly indicated for defects and areas: nasolabial folds, marionette lines, temples, remodelling facial contours, lips. DERMA SECRET EXTRA STRONG for the correction of very deep wrinkles on the face and to restore facial volume. Particularly indicated for defects and areas: cheekbone, malar region, sub-zygomatic region, sub-malar region, chin. DERMA SECRET VOLUME for the correction of wider-spread skin imperfections that affect large volumes and the body. DERMA SECRET SUPER LIGHT for the correction of slight depressions and skin imperfections of the face.

Particularly indicated for defects and areas: photoaging and chronoaging of the face, asphyctic and dehydrated skin.

Contraindications

DERMA SECRET must not be used: for injections in the periorbital zone (eyelids, under eye bags); for injections in blood vessels; for augmentations of the mammary tissue or for bone, tendon, ligament or muscle implants. DERMA SECRET must not be administered to patients with: previous or current autoimmune diseases or being treated with immunotherapeutic drugs; proven tendency to form hypertrophic scars or keloids or pigmentation disorders; multiple serious allergies; infections and inflammatory processes in situ or near the area being treated; coagulation disorders; recognised hypersensitivity to hyaluronic acid. DERMA SECRET must not be used by women who are pregnant, nursing or on people under the age of 18.

Warnings

DERMA SECRET is only intended to be injected subcutaneously or intradermally and must not be injected intravascularly. In performing the injection procedure, there is a potential risk that the material gets inadvertently injected into the blood vessels. In rare cases this could cause vascular occlusion, abscess, necrosis or embolic phenomena. To ensure that the needle is not inside a blood vessel during normal use of the medical device, lightly aspirate with the syringe before proceeding with the injection. DERMA SECRET was packaged to be used on one patient only and within the same session. DERMA SECRET is supplied as a single-use sterile product and must not be re-sterilised. Do not re-use. Use DERMA SECRET immediately after opening the blister pack and discard the syringe immediately after use, even if the entire contents have not been used. Do not use the product past the expiry date shown on the package or if said package is damaged, opened or stored improperly. Do not use DERMA SECRET in combination with other injectable products or mix it with other preparations before use. Do not use DERMA SECRET when the skin shows redness, swelling or changes in pigmentation; do not use DERMA SECRET with inflammation, infection or fever in progress. Patients taking medications to slow blood clotting may present with bruising or significant bleeding at the injection site. Patients taking anticoagulant medication should stop taking it, in agreement with their doctor, at least 14 days before getting DERMA SECRET injections.

INCOMPATIBILITY: there is a recognised incompatibility between hyaluronic acid and quaternary ammonium salts such as benzalkonium chloride. Therefore avoid contact of DERMA SECRET with these substances or using medical-surgical material containing quaternary ammonium salts. Keep out of the reach of children.

Precautions for use

Only use DERMA SECRET in compliance with these instructions for use. DERMA SECRET is a colourless transparent gel: if the contents of the syringe appear altered or contain particles, do not use it and inform VIDA S.r.l. at the address below. Do not use the device if

the syringe or blister it is contained in is damaged. Follow all normal handling precautions associated with intradermal injection procedures. Injection is associated with an inherent risk of infection. The skin must be perfectly clean and disinfected before treatment. Do not use on patients with ongoing infections or inflammatory processes near or at the injection site. It is recommended not to use DERMA SECRET in areas where other implants have been performed and not to use it at the same time as any other injectable product. The patient should not wear makeup for the 24 hours following the injection and should be informed that, during the remission period, or until the swelling or redness has completely disappeared, he/she should avoid exposing the treated area to direct sunlight, UV lamps or cold. If a laser, chemical peel or dermabrasion treatment is carried out after using DERMA SECRET, an inflammatory reaction may occur. For the same reason DERMA SECRET should be used only when the sequelae of any previous treatment have completely subsided.

After use, syringes and needles can pose a potential biological hazard. Handle with care and dispose of in accordance with approved medical practice.

Adverse reactions

Before starting treatment, the doctor must inform the patient that there are potential secondary effects related to intradermal implant that may occur immediately or after some time. Following the use of DERMA SECRET, some injection-related adverse reactions may occur, which include pain, itching, altered pigmentation and tissue density in the area of the injection site and which normally resolve spontaneously within a week. Sometimes small oedemas may appear, which reabsorb in few days. Adverse reactions related to the use of the product, in consideration of the bibliographic studies of the existing literature and the scientific knowledge of the producer at the date of issue of this leaflet, can include the following: inflammatory reactions, itching, pain to the touch after injection lasting up to a week at most; bleeding or haematoma in rare cases; follicular papules-pustules that may form up to 4 weeks after treatment; allergic reactions to hyaluronic acid; hardening or appearance of nodules at the injection site; in very rare cases, granulomas or significant inflammatory reactions, wheals, necrosis, urticaria, which can appear even after 2-4 weeks.

IMPORTANT: patients should tell their doctor about any type of serious adverse reaction or otherwise not listed in this leaflet, and the doctor, in addition to prescribing the appropriate treatment for these reactions, has the obligation to inform the distributors and the manufacturer VIDA Srl.

How to use

Before starting treatment, the doctor must inform the patient about the composition, characteristics, precautions for use, warnings, contraindications and potential adverse reactions associated with this device. Furthermore, the doctor must first take a medical history and perform an evaluation of any previous immunological or allergic problems of the patient and ascertain compatibility with the use of DERMA SECRET. Finally, the doctor must evaluate the skin areas involved in the treatment to ascertain patient suitability for the implant and the actual usefulness of such treatment. DERMA SECRET can only be administered by qualified medical personnel. For a correct final result of the treatment it is essential to proceed with a correct injection technique. Before the injection, disinfect the area to be treated with alcohol or other antiseptic solutions. The product must be injected using a sterile syringe equipped with a fine needle. For DERMA SECRET LIGHT we recommend using a 30G needle, for DERMA SECRET SOFT a 27G or 30G needle, for DERMA SECRET STRONG a 27G or 25G needle, for DERMA SECRET EXTRA STRONG a 25G needle, for DERMA SECRET VOLUME an 18G cannula, for DERMA SECRET SUPER LIGHT a 30G needle. However, the choice of needle and the method of injection is at the discretion of the doctor. The amount of product to be injected must be established according to the depth of the wrinkle or skin lesion and can be easily dosed thanks to the use of graduated syringes. Immediately after performing the injections, firm pressure and massage of the treated part should be applied/carried out in order to promote homogeneous distribution of the product. Before each procedure the symmetry of the selected areas of the face must be carefully evaluated, planning to inject the same amount of material on the right and left, and at symmetrical points. Immediately before performing the implant, remove the syringe from the protective blister, unscrew the syringe cap and position the needle by screwing the needle cone onto the syringe Luer-lock attachment until you feel resistance. For safe use of DERMA SECRET it is important to use an appropriate needle and assemble the needle correctly on the syringe, as incorrect assembly may cause the needle to detach from the syringe during injection. Remove the protective cap from the needle only before injection. Do not use needles that are not sterile, bent, warped or if packaging is not perfectly intact. Before injection, expel air from the syringe until a drop of product comes out from the tip of the needle. Insert the needle at an angle of 30 degrees; following exactly the course of the wrinkle or depression and inject the product into the middle dermis. If hyaluronic acid is administered too deeply, the final effect lasts less over time; on the contrary, if it is injected too superficially, nodules or granulomas can form. Never apply excessive pressure on the syringe; inject DERMA SECRET while the needle is slowly being retracted, depositing a homogeneous amount of product along the chosen site. Stop applying pressure to the syringe plunger before removing the needle from the skin to avoid spilling material from the injection point. In case of immediate swelling it is helpful to briefly apply cold compresses. Note: the graduation on the syringe is not provided for measuring purposes, but only as a

visual check of the injected material.

Dosage

The dosage depends on the condition of the patient's skin and the depth of the area to be treated. Optimal results can be obtained by repeating the treatment on a regular basis over time, taking into account the different factors that contribute to the long-lasting efficiency of the injection, such as lifestyle, physical activity, exposure to sun rays or tanning lamps, age and appropriate filling technique.

Packaging

One package of DERMA SECRET contains: one pre-filled syringe containing the product, 1mL-graduated syringe, for DERMA SECRET LIGHT, DERMA SECRET SOFT, DERMA SECRET STRONG, DERMA SECRET EXTRA STRONG and DERMA SECRET SUPER LIGHT, while it is 10mL-graduated for DERMA SECRET VOLUME. The syringe comes with a Luer-Lock attachment inside a blister and is provided with an adhesive label. A set of two adhesive labels showing the batch number and expiry date, one of which must be applied to the patient's medical file and the other must be given to the patient. These procedures must be strictly performed to ensure product traceability. Instructions for use to be read carefully before using the device. Two 30G needles for DERMA SECRET LIGHT and DERMA SECRET SUPER LIGHT, two 27G needles for DERMA SECRET SOFT and DERMA SECRET STRONG, two 25G needles for DERMA SECRET EXTRA STRONG.

Storage conditions

Read the expiry date of the product on the adhesive label of the syringe and on the packaging. Store in a dry place, away from direct light and at a temperature between 5°C-25°C.

Symbols on the package



Manufacturer



Refer to the instructions for use



Attention, refer to the documents attached to the device



Do not re-use



Do not use if package is damaged



Store in a dry place



Keep away from direct sunlight



Expiration date



Batch number



Storage temperature range



Steam or dry heat sterilised



Do not re-sterilise



CE marking compliant with directive 93/42/EEC on medical devices. 0373 is the number of the Notified Body

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Vida S.r.l.

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Derma Secret

Golden Pharm S.A.L.