Surgiderm®

ALLERGAN

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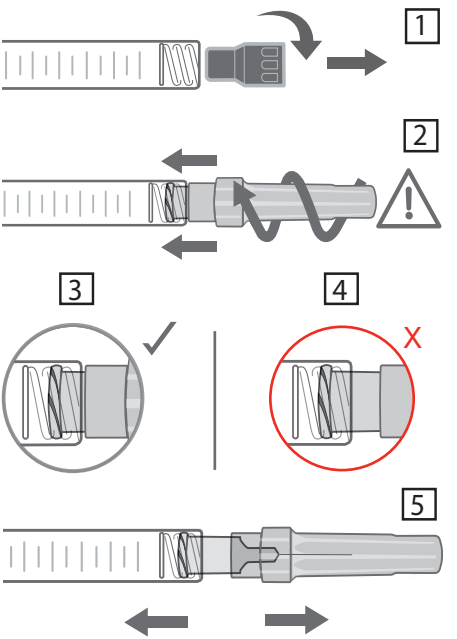
ALLERGAN
Route de Promery
Zone Artisanale de Pré-Mairy
74370 PRINGY-FRANCE
Tel : (33) 04 50 27 27 03
Fax : (33) 04 50 27 26 89

CE
0459
(2005)

72356JR11C

Only for professional use



COMPOSITION

SURGIDERM® 18	Hyaluronic acid gel: 18 mg - Phosphate buffer pH 7.2 q.s. 1 mL - One syringe contains 0.8 mL.
SURGIDERM® 24XP	Hyaluronic acid gel: 24 mg - Phosphate buffer pH 7.2 q.s. 1 mL- One syringe contains 0.8 mL.
SURGIDERM® 30	Hyaluronic acid gel: 24 mg - Phosphate buffer pH 7.2 q.s. 1 mL - One syringe contains 0.8 mL.
SURGIDERM® 30XP	Hyaluronic acid gel: 24 mg - Phosphate buffer pH 7.2 q.s. 1 mL - One syringe contains 0.8 mL.

DESCRIPTION

SURGIDERM® 18 / 24XP / 30 and ***30XP*** are sterile pyrogen-free physiological solutions of cross-linked hyaluronic acid which is not of animal origin. The gel is presented in a graduated pre-filled disposable syringe.

Each box contains an instruction leaflet and a set of labels in order to ensure traceability and:

- For ***SURGIDERM® 18***, two 0,8mL syringes and four single-use 30G1/2" sterile needles.
- For ***SURGIDERM® 24XP***, two 0,8mL syringes with four single-use 30G1/2" sterile needles
- For ***SURGIDERM® 30***, two 0,8mL syringes and four single-use 27G1/2" sterile needles,
- For ***SURGIDERM® 30XP***, two 0,8mL syringes and four single-use 27G1/2" sterile needles.

STERILISATION

The contents of the ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** syringes are sterilised by moist heat.

The 30G1/2" and 27G1/2" needles are sterilised by radiation.

INDICATIONS

SURGIDERM® 18	Injectable implant indicated for filling superficial skin depressions by injection in the superficial dermis. Can be also used in Mesolift applications.
SURGIDERM® 24XP	Injectable implant used for filling any medium depression of the skin via mid-dermis injection, as well as for definition and pouting of the lips.
SURGIDERM® 30	Injectable implant used for filling any deep depression of the skin via deep dermis injection, as well as for lip enhancement and cheekbone augmentation.
SURGIDERM® 30XP	Injectable implant used for filling mid and/or deep depression of the skin via mid and/or deep dermis injection, as well as for volume increase, definition and pouting of the lips.

CONTRA-INDICATIONS

SURGIDERM® 18	Do not inject in the eyelids. The application in the bags under the eyes is reserved to specialists specifically trained in this technique and having a sound knowledge of the physiology for this particular area.
SURGIDERM® 24XP	Do not inject in the eyelids. The application in the bags under the eyes is reserved to specialists specifically trained in this technique and having a sound knowledge of the physiology for this particular area.
SURGIDERM® 30	Do not inject in the periorbital area (eyelids, bags under the eyes, eye wrinkles) and glabellar region.
SURGIDERM® 30XP	Do not inject in the periorbital area (eyelids, eye wrinkles) and glabellar region (forehead). The application in the bags under the eyes is reserved to specialists specifically trained in this technique and having a sound knowledge of the physiology for this particular area.

In addition,

- Do not inject into the blood vessels (intravascular).
- Do not overcorrect.
- ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** must not be used in :

- patients who tend to develop hypertrophic scarring ;
- patients who are known to be hypersensitive to hyaluronic acid ;
- women who are pregnant or breastfeeding ;
- children.

- ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** must not be used in areas presenting cutaneous inflammatory and/or infectious processes (acne, herpes...).
- ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** should not be used simultaneously with laser treatment, deep chemical peels or dermabrasion. For surface peels, it is recommended not to inject the product if the inflammatory reaction generated is significant.

PRECAUTIONS FOR USE

SURGIDERM® 18 / 24XP / 30 and ***30XP*** are not indicated for injections other than intra-dermal injections and in lips.

- As a matter of general principle, injection of a medical device is associated with a risk of infection.
- There is no available clinical data (efficiency, tolerance) about injection of ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** into an area which has already been treated with another filling product. It is recommended not to inject it in site which has been treated with a permanent implant.
- No clinical data is available regarding the efficiency and tolerance of ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** injections in patients having a history of or currently suffering from autoimmune disease. Depending on the nature of the disease, the medical practitioner shall therefore decide on the administration and associated treatment on an individual case-by-case basis. He/she shall also ensure the specific monitoring of this type of patients. In particular, it is recommended that these patients undergo a preliminary test, and to refrain from injecting the product if the disease is active.
- There is no available clinical data concerning the tolerance of the ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** injection in patients presenting a history of severe multiple allergies or anaphylactic shock. The medical practitioner must therefore decide on the indication according to the individual case, depending on the nature of the allergy, and must ensure that there is individual surveillance of these patients who are at risk. In particular, the decision may be taken to propose a double test or preventive adapted treatment previously to any injection.
- Patients showing a history of streptococcal disease (recurrent sore throats, acute rheumatic fever) shall be subjected to a test before any injection is given to them. In the event of acute rheumatic fever with heart complications, it is recommended not to inject the product.
- Patients on anti-coagulation medication (anticoagulants, aspirin, or nonsteroidal anti-inflammatory drugs) must be warned of the potential increase risks of haematomas and bleeding during injection.
- There is no data available regarding the safety of injecting greater amount than 20 mL of ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** per 60 kg (130 lbs) body mass per year.
- Please recommend the patient not to use any make up during the 12 hours that follow the injection treatment and to avoid any extended exposure to the sun, UV rays and temperatures below 0°C, as well as any sauna or hammam session during the two weeks that follow the injection treatment.
- If the needle is blocked, do not increase the pressure on the plunger rod but stop the injection and replace the needle.
- The composition of this product is compatible with fields used for magnetic resonance imaging.

INCOMPATIBILITIES

Hyaluronic acid is known to be incompatible with quaternary ammonium salts such as benzalkonium chloride. ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** should never therefore be placed in contact with these substances or with medical-surgical instrumentation which has been treated with this type of substance.

UNDESIRABLE EFFECTS

The patients must be informed that they are potential side effects associated with implantation of this product, which may occur immediately or may be delayed. These include (non-exhaustive list) :

• Inflammatory reactions (redness, oedema, erythema, ...) which may be associated with itching, pain on pressure, occurring after the injection. These reactions may last for a week.

• Haematomas.

• Induration or nodules at the injection site.

• Staining or discolouration of the injection site.

• Poor effect or weak filling effect.

• Cases of necrosis in the glabellar region, abscesses, granuloma and immediate or delayed hypersensitivity after injections of hyaluronic acid having been reported, it is advisable to take these potential risks into account.

• Patients must report inflammatory reactions which persist for more than one week, or any other side effect which develops, to their medical practitioner as soon as possible. The medical practitioner should use an appropriate treatment.

• Any other undesirable side effects associated with injection of ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** must be reported to the distributor and/or to the manufacturer.

METHOD OF USE – POSOLOGY

• This product is designed to be injected into the dermis by an authorized medical practitioner in accordance with local applicable regulation. As precision is essential to a successful treatment, the product must be used by medical practitioners who have undertaken specific training in injection techniques for filling.

The nappage technique can also be used with ***SURGIDERM® 30XP***.

• ***SURGIDERM® 18 / 24XP / 30*** and ***30XP*** are to be used as supplied. Modification or use of the product outside the Directions for Use may adversely impact the sterility, homogeneity and performance of the product and it can therefore no longer be assured.

• Before performing treatment, the patient should be informed of the product's indications, contra-indications, incompatibilities, and potential side effects.

• The area to be treated should be disinfected thoroughly prior to the injection.

• Remove tip cap by pulling it straight off the syringe as shown in fig. 1. Then firmly push the needle provided in the box (fig. 2) into the syringe, screwing it gently clockwise. Twist once more until it is fully locked and has the needle cap in the position shown in fig. 3. If the needle cap is positioned as shown in fig. 4, it is incorrectly attached.

Next, remove the protective cap by holding the body of the syringe in one hand, the protective cap in the other, as shown in fig. 5, and pulling the two hands in opposite directions.

Inject slowly.

Failure to comply with these precautions could cause a disengagement of the needle and/or product leakage at luer-lock level.

• The amount injected will depend on the areas which are to be corrected.

• It is important to massage the area treated after the injection in order to ensure that the substance has been uniformly distributed.

WARNINGS

• Check the expiry date on the product label.

• Do not re-use. Sterility of the device can not be guaranteed if is re-used.

• Do not re-sterilise.

• For the needles (CE 0123 TSK Laboratory, Japan):

EC-Representative : Emergo Europe
Molenstraat 15
2513 BH The Hague (NL)

- Used needles must be thrown away in the appropriate containers. Do the same for the syringes. Please consult the current directives in force to ensure their correct elimination.

- Never try to straighten a bent needle, throw it away and replace it.

STORAGE CONDITIONS

• Store between 2°C and 25°C.

• Fragile.