Formaderm® Dermal Filler Injection

Read this package insert completely before use and comply with the instructions for use.

GRAPHICAL SYMBOLS	
Single use only	REF Catalog number
Read instructions before use	LOT Lot number
STERILE A Sterilization using aseptic	Store at 2~8°C
Do not re-sterilize	Keep away from sunlight
Use by expiry date	Do not use if package is damaged
	Manufacturer

Description

Formaderm® is a clear, transparent and viscous gel of non-animal, stabilized hyaluronic acid (NASHA). Hyaluronic acid is a natural polysaccharide which occurs as an important structural element in the skin and in subcutaneous and connective tissues as well as in the synovial tissue and fluid. Hyaluronic acid belongs to a group of very few substances which are identical in all living organisms. Formaderm® is supplied in a glass syringe with one 27G and one 30G disposable sterile needles. The content of the syringe has been sterilized by steam. This product is for single use only.

Composition		Specification	
Sodium Hyaluroniate	20 mg/ml	FD-1100	1.0 ml/syringe
Phosphate Buffered Saline	q.s.	FD-1150	1.5 ml/syringe
pH	6.8 – 7.5	FD-1200	2.0 ml/syringe

Indication and usage

Formaderm® is indicated for use as a filler for facial tissue augmentation. It is recommended that Formaderm® be used for wrinkles correction and for lip enhancement. Formaderm should be injected into the middle part of the dermis layer of facial skin. With cutaneous contour deformities the best results are obtained if the defect can be manually stretched to the point where it is eliminated. The degree and duration of the correction depend on the character of the defect treated, the tissue stress at the implant site, the depth of the implant in the tissue and the injection technique.

Made of action

Formaderm® acts as by adding volume to the tissue, thereby restoring the skin contours or enhancing the lips to the desired level of correction. Formaderm® is naturally integrated into the tissue and will in time undergo isovolemic degradation.

Warning

- Formaderm® is only intended for use as an intradermal implant.
- Do not re-sterilize Formaderm.
- Do not mix with other products.
- Do not inject intravascularly. Vascular occlusion, ischemia and necrosis may occur if Formaderm is injected into vessels. Aspiration prior to injection is recommended.
- Injection should be stopped if blanching is observed.
- Do not use in patients with bleeding disorder. Do not use in patients who are taking thrombolytics or anticoagulants.

General consideration relevant to injectable medical devices

- Injection procedures are associated with and inherent risk of infection. Normal precautions associated with injections must be bserved.
- Special cautions should be exercised when treating areas in close proximately to permanent implant or vulnerable structures such as nerves, vessels and other vital structures.
- Do not use where there is active disease such as inflammation, infection or tumors, in or near the intended treatment site.
- Injection procedures can lead to reactivation of latent or subclinical herpes viral infection.
- Patients who are using substances that affect platelet function such as aspirin and non-steroidal anti-inflammatory drugs may, as with any injection, experience increased bruising or bleeding at injection sites.
- Patients with unattainable expectations are not suitable candidates for treatment.
- Do not use the product if package is damaged.

Specific considerations relevant to the use of Formaderm

- Formaderm® should not be injected into an area where another injectable implant has been placed, except for other products from Formaderm® range of products.
- Formaderm® should not be injected into an area where a non-injectable or permanent implant has been placed.
- The patient should be informed that he or she should minimize exposure of the treated area to intense heat (e.g. solarium and sunbathing) or extreme cold at least until the initial swelling and redness have resolved.
- If laser treatment, chemical peeling or any other procedure based on active dermal response is performed after treatment with Formaderm® there is a theoretical risk of eliciting an inflammatory reaction at the implant site. This also applies if Formaderm® is administered before the skin has healed completely after such a procedure.
- Formaderm® has not been tested in pregnant or lactating women or in children.

Anticipated side-effects

After the injection of Formaderm®, some common injection-related reactions might occur. These reactions include erythema, swelling, pain, itching, discoloration or tenderness at the implant site. Typically resolution is spontaneous within a few days after injection into the skin and within a week after injection into the lips.

Assembly of needle to syringe

For safe use of Formaderm® it is important that the needle is properly assembled.

1. Unscrew the tip cap of the syringe carefully.
2. Take a loose grip on the narrow part of the needles shield and mount the needle on the luer-lock by screwing until you feel some counterpressure.
3. Take a new firm grip on the wide part of the needle shield. Press and turn it a further 90°.
4. Pull off the needle shield.

Dosage and administration

- The patient's suitability for the treatment and the need for pain relief should be assessed before the treatment.
- Normally, anaesthesia is not necessary when treating wrinkles. For lip augmentation, anaesthesia through a nerve block can be used.
- The patient should be informed about the indication, expected result, contraindications, precautions, warnings and potential adverse events.
- The treatment site should be cleaned with a suitable antiseptic solution.
- Formaderm® is administered using a needle (27G or 30G) by injecting the material into the dermis. Before injecting, press the rod carefully until a small droplet is visible at the tip of the needle.
- The injection technique with regard to the depth of injection and the administration quantity may vary. The linear threading technique can be used to carefully lift up the wrinkle, but some physicians prefer a series of punctual injections or combination of the two.
- Inject Formaderm® while pulling the needle slowly backwards.
- Injection should stop just before the needle is pulled out from the skin to prevent material from leaking out from the injection site.
- Defects should be fully corrected but not overcorredted at each treatment session.
- If the skin of the patient is very loose, it is recommended that Formaderm® be injected on two separate occasions.
- The correction site should be massaged to conform to the contour of the surrounding tissues.
- For each treatment site a maximum dosage of 2mL per treatment session is recommended.
- After the first treatment, additional implantations of Formaderm® may be necessary to achieve the desired level of correction.
- Periodic follow-up injections help sustain the desired degree of correction.

Note

- The correct injection technique is important for the final result of the treatment.
- Formaderm® is only intended to be administrated by authorized personnel in accordance with local legislation.
- The syringe, the needle and any unused material have to be discarded directly after the treatment session. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

Shelf life and storage

As indicated on package. Store up to 2-8℃. Protect from freezing and sunlight.

MBI Maxigen Biotech Inc.

17, Wuchiuan 8th Rd., Wugu District, New Taipei City 24891, Taiwan R.O.C
Tel: 886-2-2298-2345
Fax: 886-2-5591-9522