

Profiller Lips

Hyaluronan Soft Tissue Filling Gel

PRODUCT NAME

PROFILLER LIPS Hyaluronan Soft Tissue Filling Gel

DESCRIPTION

PROFILLER LIPS is a colorless, transparent, viscoelastic, biodegradable, non-pyrogenic and sterile gel, supplied in a prefilled glass syringe. PROFILLER LIPS consists of cross-linked sodium hyaluronate from biofermentation and formulated to a concentration of 20 mg/ml, suspended in a physiological buffer at pH 7. Sodium hyaluronate is a natural polymer of repeating disaccharide units of N-acetyl-D-glucosamine and sodium glucuronate linked by glycosidic bonds, which is widely distributed in the extracellular matrix in both animals and human. After slightly cross-linking, it also has good biocompatibility. PROFILLER LIPS is supplied in a disposable glass syringe with a luer-lock fitting. The syringe is equipped with a plunger stopper, finger grip and plunger rod and packed in a blister together with two sterile needles, 27Gx1/2".

INDICATIONS

PROFILLER LIPS is indicated to be used for lip defects or volume enhancement.

CONTRAINDICATIONS

Do not inject into the eye contours (eye circle or eyelids). Do not inject into the blood vessels (intravascular). Must not be used in: - women who are pregnant or breastfeeding - people under age of 18 - patients who are known to be hypersensitive to Hyaluronic acid - patients who tend to develop hypertrophic scarring. Must not be used in association with laser therapy, chemical peeling or dermabrasion. Must not be used in areas presenting cutaneous inflammatory and infectious processes.

SPECIFICATION CONTENT:

Sodium hyaluronate, cross-linked: 20 mg/ml - Physiological sodium chloride phosphate buffer: q.s. - pH: 6.8 - 7.5 - Volume: 1.0 ml One package of PROFILLER LIPS contains a syringe and two sterile 27Gx1/2" needles.

MODE OF ACTION

After injection, PROFILLER LIPS integrates into the tissue naturally, and acts by adding volume to dermal tissue, thereby restoring wrinkles and folds to the desired correction.

PRE-TREATMENT GUIDANCE

Before the treatment, the suitability of patient for treatment should be assessed. The patient should be informed of the indications, precautions, warnings, and potential side-effects. According to the depth of injection and the administered quantity, a linear threading technique, a serial puncture technique, or a combination of the two can be used at the discretion of doctors.

DOSAGE

Defects should be fully corrected but not overcorrected, a maximum dosage of 1.5 ml per injection site is recommended.

TREATMENT PROCEDURE

PROFILLER LIPS should be used after indoor temperature balance. Local analgesia (ice, topical analgesics or local infiltration, and/or nerve block with 1% lidocaine solution) is provided before treatment at the discretion of the doctor. Before injection, press the rod carefully until a small droplet is visible at the tip of the needle. Inject PROFILLER LIPS while pulling the needle slowly backwards and stop injecting just before the needle is pulled out from the skin to prevent material from leaking out from the injection site. Once the injection is completed, the injection site is manually massaged to allow PROFILLER LIPS to conform to the contours of the adjacent tissues. After injection, if the treated area is swollen, melting ice can be applied on the site for a short period.

PRECAUTIONS

The correct injection technique is crucial for the final result of the treatment. Individual differences will affect the final result of the treatment. If additional implantations of PROFILLER LIPS are necessary, the minimum time interval between the first and additional injection is 2-4 weeks. Clean the area to be treated with alcohol or another suitable antiseptic solution. As with all transcutaneous procedures, PROFILLER LIPS implantation carries a risk of infection. The safety of PROFILLER LIPS used during pregnancy, in breastfeeding females or in patients under 18 years has not been established. PROFILLER LIPS should not be used in patients with known susceptibility to keloid formation or hypertrophic scarring. PROFILLER LIPS should be used with caution in patients on immunosuppressive therapy and patients who are using substances that reduce coagulation. After treatment, the patient should minimize exposure of the treated area to UV lamp and excessive sunlight and extreme cold weather until any initial reaction has resolved. After treatment with PROFILLER LIPS, patient should not receive laser treatment, chemical peeling or any other procedure based on active dermal response. Patients with a severe allergic reaction should not receive treatments of PROFILLER LIPS. PROFILLER LIPS should not be injected too deeply or too superficially. After injection, used syringes and needles should be handled as medical waste according to local and state requirements. Clinical investigation confirms that the first injection of PROFILLER LIPS is safe. It is reported that repeated injection of the same kind filler in the same region do not pose an increased risk for adverse reactions in literature.

WARNING

PROFILLER LIPS is for single use only. Do not use if package is opened or damaged. Do not resterilize PROFILLER LIPS as this may damage or alter the product. Do not inject intravascularly. Do not use PROFILLER LIPS with other fillers.

ADVERSE EVENTS

Hypersensitivity or allergic reactions have been rarely reported, which include oedema, tenderness and rarely acneform papules in the surrounding tissues. In pronounced cases, treatments have included systemic steroids, systemic antibiotics, and intravenous administrations of medications. Rare cases of granuloma formation, superficial necrosis and urticaria have been reported with the same kind of products, patients who have experienced this type of reaction should not be retreated.

ASSEMBLY OF NEEDLE TO SYRINGE

It is important that the needle is properly assembled for safe use of PROFILLER LIPS. Operation steps:

1. Unscrew the tip cap of the syringe carefully.
2. Peel sealed cover off the wider part of needle shield carefully.
3. Take a grip on the narrow part of the needle shield and mount the needle on the luer-lock.
4. Take a firm grip on the wider part of the needle shield and turn it a quarter of a turn clockwise.
5. Pull off the needle shield to expose needle.

STORAGE

PROFILLER LIPS has to be stored between 2 ~ 25°C in a dry place and should be protected from sunlight, heat and frost.

SHELF LIFE

36 months under recommended conditions.

ONLY FOR MEDICAL USE

LAST REVISED:

11/2019

Symbols on the label (EN ISO 15223-1:2016)	
	= Do not reuse
	= Use by
	= Sterilized using steam
	= Lot number
	= Date of manufacture
	= Temperature limitation
	= CE-marked according to MDD 93/42/EEC and identification number of Notified Body
	= Manufacturer
	= Do not use if package is damaged
	= Consult instructions for use
	= Do not re-sterilize
	= Keep away from sunlight
	= Indicates a medical device that can be broken or damaged if not handled carefully



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