



PRESS MATERIAL

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BACKGROUND

Q-MED

Q-Med was founded in 1987 by Bengt Ågerup with a view to commercializing the research that he had carried out around hyaluronic acid.

Q-Med's first product on the market is called RESTYLANE, and it was introduced in 1996. RESTYLANE is an instant esthetic treatment used for lips, wrinkles and facial contours. Since its introduction in 1996 over 1,500,000 treatments have been performed in over 60 countries.

Q-Med is a rapidly growing and profitable biotechnology/medical device company that develops, produces and markets medical implants. All products are based on the company's patented technology for the production of NASHA - Non-Animal Stabilized Hyaluronic Acid. Q-Med's operations focus on the four areas of Esthetics, Orthopedics, Uro-Gynecology, and Cell Therapy and Encapsulation.

The products RESTYLANE, RESTYLANE Touch and RESTYLANE Perlane are used for the filling out of lips and facial wrinkles and today account for the majority of sales. DUROLANE, Q-Med's product for the treatment of osteoarthritis of the knee joint, has been approved in Europe since May 2001. DEFLUX is a product which has been approved in Europe and the USA for the treatment of vesicoureteral reflux (malformation of the urinary bladder) in children. ZUIDEX for the treatment of stress urinary incontinence in women has been sold in Europe since July 2002.

Since July 2000 Q-Med has owned a majority interest in the American biotechnology company Ixion Biotechnology, Inc., with research within cell therapy for diabetes and within oxalate control.

Q-Med today has 450 employees, with approximately 300 at the company's production facility and head office in Uppsala, 15 at Ixion and the remainder in wholly owned foreign sales companies. The Q-Med share was first listed on the O-list of the Stockholm Stock Exchange in December 1999.



BACKGROUNDER

RESTYLANE

RESTYLANE offers a complete solution for treating facial lines, wrinkles, and lips. It can also be used in facial sculpting by enhancing natural facial contours and features. Known as dermal filler, RESTYLANE is manufactured by Q-Med, a growing Swedish biotechnology and medical device company. There are three treatment choices – each tailored and designed for different purposes and effects, from reducing the appearance of lines to enhancing facial contours and sculpting lips.

- RESTYLANE – for treatment of wrinkles and lip enhancement.
- RESTYLANE Touch – for correction of thin lines, across the forehead and around the eyes and mouth.
- RESTYLANE Perlane – for correcting deep folds, creating fuller lips and shaping facial contours, such as cheeks and chin.

The treatment uses injections. The gel injected is based on a biotechnologically produced version of hyaluronic acid, a tissue friendly substance that occurs naturally in the body. RESTYLANE instantly fills out the skin to reduce the effects of wrinkles and lines. The injected gel is not collagen and it is not botulinum toxin, Botox.®

RESTYLANE contains a substance known as Non-Animal Stabilized Hyaluronic Acid (NASHA). Hyaluronic acid exists naturally in our bodies and its most important function is to carry and bind water. Q-Med has developed a way of stabilizing hyaluronic acid to achieve an effect that lasts from six to twelve months in smoothing lines and around six months when used to augment lips. The effects of non-stabilised hyaluronic acid products should last only a few days or weeks at most.

Nutrients, oxygen and hormones are able to pass freely between the gel particles and the tissue, leaving the skin natural and healthy looking. As the gel breaks down, water takes its place and when totally absorbed the gel disappears unnoticed from the body. It biodegrades naturally and safely.

Non-Animal: The hyaluronic acid in NASHA is produced through a biotechnology process under laboratory conditions. The hyaluronic acid in NASHA is not extracted from animals, unlike some other versions of hyaluronic acid.



Safety: More than 1,500,000 treatments have been carried out successfully since the launch of RESTYLANE in 1996. Adverse reactions with RESTYLANE, RESTYLANE Touch and RESTYLANE Perlane are very rare. Temporary local reactions, related to hypersensitivity occur in less than 1 in 2000 treatments. Medical use of hyaluronic acid based products is also well documented in areas such as eye surgery and orthopedics.

Effective and long lasting: RESTYLANE offers instantaneous results that are long lasting but not permanent. Generally, after lip treatments, follow up is usually required after about six months. Facial contours and wrinkles normally need following up six to twelve months after the initial treatment.

Treatment procedure: During treatment, RESTYLANE is injected into the skin in tiny amounts with a very fine needle. When injected into the skin, RESTYLANE produces volume that smoothes the wrinkle or fold, shapes the facial contour or enhances the lips in a natural way. The result is immediate. The method of injecting RESTYLANE is fast and safe and leaves no scars or other traces on the face. For wrinkle treatments, pain relief is not required by all patients; however it can be easily arranged at your request. Prior to your procedure, a topical anaesthetic cream can be applied to the area to be treated. You can also choose to have a local anaesthetic injection.

Restylane

QUESTIONS AND ANSWERS

RESTYLANE

What is RESTYLANE?

RESTYLANE is a gel that is injected into the skin in order to add volume to lips and lift up wrinkles and folds. RESTYLANE consists of hyaluronic acid, which is a natural substance already present in your body. Once in the skin, RESTYLANE works by creating volume. Some dermal fillers are derived from animal substances. The hyaluronic acid in RESTYLANE is non-animal.

What are the advantages of RESTYLANE over the many other facial esthetic products?

- Natural and safe
- No animal ingredients
- No skin test needed
- Instant and long lasting results
- Biodegradable, non permanent
- Fast treatment, takes around 30 minutes
- Complete tissue tailored product range
- Clinical data supporting efficacy and safety

TREATMENT

How is a treatment performed?

During treatment, the crystal-clear RESTYLANE gel is injected into the skin in tiny amounts with a very fine needle. The gel produces volume under the wrinkle, which is lifted up and smoothed out. When enhancing lips or facial contours, RESTYLANE adds volume and shape to the treated area.

How long will the treatment session take?

Treatment with RESTYLANE is a very quick and easy process. As no pre-test is needed, the treatment can be carried out immediately. A treatment generally takes 30 minutes. The time differs somewhat, depending on the correction you wish to have performed.



What can be treated?

RESTYLANE can be used for smoothing out folds and wrinkles, lip enhancements and shaping facial contours. The most common areas are the glabellar lines (between the eyebrows), the nasolabial folds (from the root of the nose to the angle of the mouth) and the lips, but other sites can also be treated. Very superficial or very deep wrinkles may be difficult to correct. Please consult your physician for an assessment.

Does it hurt?

Most people find the injections relatively painless. They may prick a little. If you like, a topical anaesthetic can be applied to the area being treated prior to your procedure. When enhancing the lips, local anaesthetic injection is often used.

How long does the effect of a RESTYLANE treatment last?

The length of time the effect of a RESTYLANE treatment lasts is very individual and depends on many factors, such as the structure of your skin, lifestyle, age, the degree of perfection demanded and the injection technique of the practitioner. Experience indicates that touch-up and follow-up treatments will add to the duration.

Most people choose to have a new treatment within a year after the treatment of wrinkles and folds and within 6 months after a lip enhancement.

SAFETY**Are there any side-effects?**

The rate of reactions to RESTYLANE is very low. However, after the treatment some common injection-related reactions may occur, such as swelling, redness, pain, itching, discoloration and tenderness at the injection site. These typically resolve spontaneously within a few days after injection into the skin and within a week after the injection into the lips. Other types of reactions are very rare, but about 1 in 2000 treated patients have experienced localized reactions thought to be of a hypersensitive nature. These have usually consisted of swelling at the injection site, sometimes affecting the surrounding tissues. Redness, tenderness and rarely acne-like formations have also been reported. These reactions have either started a few days after the injection or after a delay of two to four weeks, and have generally been described as mild to moderate and self-limiting with an average duration of two weeks. This text does not contain all the information known about these products. For more information, please consult your practitioner.



Recommended reading:

1. A randomized, double-blind multicenter comparison of the efficacy and tolerability of Restylane[®] versus Zyplast[®] for the correction of nasolabial folds
Narins RS, Brandt F, Leyden J, Lorenc P, Rubin M, Smith S
Dermatol Surgery 2003; 29(6): 588-95
2. NASHA promising in facial soft-tissue augmentation
Fitton, A
Inpharma[®] 2002; No. 1363: 11-12
3. Safety data of injectable nonanimal stabilized hyaluronic acid gel for soft tissue augmentation
Friedman PM, Mafong EA, Kauvar ANB, Geronemus RG
Dermatol Surg 2002; 28(6): 491-4
4. NASHA - the monograph
Ågerup B, Wik O.
Q-Med, 2001
5. Erian's original technique of lip enhancement
Erian A, Ionescu NE
Int J of Cosmetic Surgery and Aesthetic Dermatology 2000; 2(1): 17-19
6. Hyaluronic acid gel injections for facial rejuvenation: A 3-year clinical experience
Cantisano-Zilkha M, Bosniak S
Operative Techniques in Oculoplastic, Orbital, and Reconstructive Surgery 1999; 2(4): 177-81
7. Restylane lip implantation: European experience
Bousquet M-Th., Ågerup B
Operative Techniques in Oculoplastic, Orbital, and Reconstructive Surgery 1999; 2(4): 172-76
8. Injectable hyaluronic acid gel for soft tissue augmentation. A clinical and histological study
Duranti F, Salti G, Bovani B, Calandra M, Rosati ML
Dermatol Surg 1998; 24(12):1317-25
9. The first clinical study using a new biodegradable implant for the treatment of lips, wrinkles and folds Olenius M
Aesth Plast Surg 1998; 22: 97-101

