

EVOLENCE®
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EVOLENCE® Questions & Answers

Q1: What is EVOLENCE®?

A1: EVOLENCE® is an advanced collagen-based structural dermal filler that provides long-lasting treatment for moderate to deep facial wrinkles and folds, such as nasolabial folds. The results of treatment with EVOLENCE® are immediate, with minimal to no downtime post-treatment, and clinically proven to last through 12 months. EVOLENCE® is the first and only collagen-based filler to provide correction through 12 months after initial treatment*.

Injected just below the skin's surface, EVOLENCE® replaces facial collagen, which naturally depletes as a person ages, with naturally sourced collagen, adding volume to contour, fill or smooth wrinkles and folds. Results offer a more refreshed, natural and youthful appearance of the skin.

EVOLENCE® represents a breakthrough in the treatment of the effects of aging due to its patented GLYMATRIX™ Technology.

Q2: What types of folds and wrinkles can EVOLENCE® treat?

A2: EVOLENCE® is recommended for the correction of moderate to deep facial wrinkles and folds, such as nasolabial folds.

Q3: How long does treatment with EVOLENCE® last?

A3: EVOLENCE® was originally launched in 2008 with a six-month duration labeling and on [DATE] the U.S. Food and Drug Administration approved a 12-month labeling supplement that includes EVOLENCE® efficacy data through one year.

Information from a U.S. clinical trial has proven that 95.3 percent and 76.5 percent of patients, respectively, maintained correction through nine and 12 months after initial treatment*. A clinical study demonstrating this 12-month duration was published in Dermatologic Surgery, June 2008 (S 31-39).

The long lasting duration of EVOLENCE® is the result of a breakthrough process called GLYMATRIX™ Technology. This proprietary process uses the natural sugar D-Ribose to cross-link purified collagen molecules. The result is a “protein scaffold” that performs the same structural function as naturally occurring collagen – providing the skin with shape, structure, support and strength – and with greater longevity than existing collagen fillers.

* Initial treatment is defined as a single treatment with the option of touch-up within two to three weeks to achieve optimal correction..

Q4: What is GLYMATRIX™ Technology and how does it work?

A4: GLYMATRIX™ Technology is a unique patented procedure used for developing EVOLENCE® that mimics the formation of the body’s own collagen. As in the human body, which uses Glucose, a blood sugar, for stabilizing proteins to strengthen tissues (a process known as cross-linking), GLYMATRIX™ Technology uses the natural sugar D-Ribose to cross-link purified collagen molecules. The result is a “protein scaffold” that performs the same structural function as naturally occurring collagen – providing the skin with shape, structure, support and strength – and with greater longevity than existing collagen fillers.

Q5: What distinguishes EVOLENCE® from other dermal fillers?

A5: While other dermal fillers are often based on hyaluronic acid, EVOLENCE® is made from one of nature’s most abundant building blocks – collagen, a natural skin protein that constitutes up to 80 percent of the skin’s structural scaffold that helps give skin its strength, structure and support.

By replacing depleted facial collagen with naturally sourced collagen, EVOLENCE® mimics the natural support structure of the facial skin, allowing it to integrate very quickly with existing tissue without migrating from the area in which it was injected.

The naturally sourced porcine collagen used in EVOLENCE® is the most genetically similar to human collagen and has been used safely and effectively for decades in various medical applications, including heart valve replacement.

Treatment with EVOLENCE® is associated with minimal to no swelling or bruising following the procedure, giving patients the freedom to carry on with their day and enjoy immediate results of a more naturally refreshed and younger looking appearance.

Q6: What is collagen?

A6: Collagen is a protein naturally found in the connective tissue that helps give skin its strength, structure and support. Up to 80 percent of the inner layer of the skin, called the dermis, is made up of collagen.

Collagen naturally depletes as a person ages, the pace of which may be affected by internal and external factors including genetics or hormonal changes, as well as the degree of sun damage, smoking and skin damage due to pollution. This on-going collagen loss leads to the appearance of lines, folds, wrinkles and changes in facial contour.

Additionally, no skin pre-test is required. The first step of the unique GLYMATRIX™ Technology purifies the naturally sourced porcine collagen, removing molecules that could potentially cause an allergic reaction.

Physicians who have used EVOLENCE® have told us that there is a need for a product like EVOLENCE® in their tool kit of aesthetic options as EVOLENCE® delivers precise, natural-looking correction with little to no downtime and minimal bruising and swelling.

Q7: Is there a need for a new type of collagen-based dermal fillers?

A7: Many physicians and their clients like collagen dermal fillers because of the natural look and feel, as well as minimal bruising and swelling immediately after the treatments. Prior collagen fillers, however, have historically been associated with a short duration of results. As the only collagen filler to last through 12 months, EVOLENCE® provides a natural and long-lasting collagen solution. Additionally, EVOLENCE® treatment does not require skin pre-testing.

Q8: Is EVOLENCE® safe?

A8: EVOLENCE® has been approved by the FDA as Safe and Effective.

EVOLENCE® is proven to be highly biocompatible and possesses a favorable safety profile. It has undergone extensive biocompatibility testing, including cytotoxicity, genotoxicity, acute systemic toxicity, sensitization, intramuscular, intracutaneous and intradermal reactivity tests.

Results of a skin hypersensitivity study using EVOLENCE® published in Dermatologic Surgery, Dec. 2007 clinically proved that among study assessments of 519 patients, no significant reactions suggestive of positive hypersensitivity from an EVOLENCE® injection were observed. Because EVOLENCE® has a low potential for hypersensitivity, there is no need for a skin pre-test required for treatment.

Q9: Who manufactures and markets EVOLENCE®?

A9: EVOLENCE® is marketed in the United States by Ortho Dermatologics division of Ortho-McNeil-Janssen Pharmaceuticals, Inc. This innovative collagen structural dermal filler was developed by ColBar LifeScience, Ltd., a biotechnology company specializing in reconstructive medicine and tissue engineering. The company has perfected a technique in which collagen, a main building block of living organisms, can be purified and transformed so as to create a variety of products that are structurally stable and safe for medical applications. ColBar LifeScience Ltd. is a subsidiary of Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Q10: How was EVOLENCE® named?

A10: The EVOLENCE® Brand name is the synthesis of the words “**EVOLUTION**” and “**CONFIDENCE**.” The Company believes the name is a perfect distillation of what this proposition represents: an **evolution** in the treatment of aging through advanced collagen-based structural dermal fillers, and the **confidence** that results from a naturally younger looking appearance.

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