

EVOLENCE® Collagen Filler
(Injectable GLYMATRIX™ Collagen Dermal Filler)

PATIENT INFORMATION

Review this brochure carefully before beginning your EVOLENCE® Collagen Filler Treatment

The information in this brochure is not meant to replace information provided by your healthcare provider. You should always ask your healthcare provider about your treatment and care

GLOSSARY

Anesthetic: A product that can cause a temporary loss of feeling or awareness. Anesthetics can be applied topically or injected for a local effect.

Collagen: The most common protein found in the body. Collagen is used to form a framework to support cell and tissue growth.

Crosslinking: Linking two different elements to create a new matrix/structure.

Dermal Filler: A product that is injected underneath the skin. Fillers are used to decrease the appearance of fine lines or wrinkles.

GLYMATRIX™: The unique patented technology used in **EVOLENCE®** to crosslink the collagen with sugar (ribose) to provide strength and long-lasting characteristics.

Hyaluronic Acid (HA) based filler – Filler made using a natural, complex sugar found within the body

Induration: A hard or thick area of the skin or tissue.

Injection: When a product is given with a needle.

Natural: Found in nature.

Porcine: Of pig origin. Medical products of porcine origin include heart valves, wound dressings, and lens implants.

Ribose: Ribose is a natural sugar and building block used by the body.

Side Effect: An unwanted event caused by the use of a product.

Synthetic: Man made.

WHAT IS EVOLENCE® COLLAGEN FILLER?

EVOLENCE® collagen dermal filler products are used to correct facial wrinkles and folds. **EVOLENCE®** is made of highly purified porcine collagen that is crosslinked via GLYMATRIX™ technology to provide long lasting results.

WHAT IS EVOLENCE® COLLAGEN FILLER USED FOR?

EVOLENCE® is injected into areas of facial tissue where moderate to deep facial wrinkles and folds occur.

WHO CAN BENEFIT FROM EVOLENCE® COLLAGEN FILLER TREATMENT?

EVOLENCE® may be appropriate for patients who want soft, supportive foundation to fill areas where there has been natural collagen loss. Your healthcare provider can help you determine if you are a good candidate for **EVOLENCE®** treatment.

DO I NEED A SKIN TEST BEFORE USING EVOLENCE® COLLAGEN FILLER?

No. Skin test studies showed that reactions to **EVOLENCE®** are rare and, when they do occur, mild. Skin testing is not necessary prior to treatment. However, in case you have had an allergy to collagen product in the past (such as hives or swelling after eating porcine products) or serious recurrent nonspecific allergic reactions, please inform your healthcare provider before treatment.

WHAT SHOULD MY HEALTHCARE PROVIDER WARN ME ABOUT?

- **EVOLENCE®** should be used with caution in patients on immunosuppressive therapy (medication commonly prescribed for those who have undergone an organ transplant, or are suffering from rheumatoid arthritis, psoriasis, inflammatory bowel disease, or cancer).
- The safety and effectiveness of **EVOLENCE®** for the treatment of areas other than facial wrinkles and folds have not been established in controlled clinical studies.
- **EVOLENCE®** should be used with caution in patients with known connective tissue disease, such as rheumatoid arthritis, scleroderma or systemic lupus erythematosus, history of herpes.
- The safety of **EVOLENCE®** in pregnant or breastfeeding women as well as in patients under the age of 18 years has not been established.

CAN EVOLENCE® BE USED IN SKIN OF COLOR PATIENTS?

The safety of **EVOLENCE®** Collagen Filler in skin of color patients (*i.e.*, individuals with skin tone of light brown to black) was studied for a limited time only (2 weeks to 3 months, 3 to 6 months, and greater than 6 months). **EVOLENCE®** should not be used in patients with known susceptibility to abnormal scarring or local changes in skin color. The safety of **EVOLENCE®** in patients susceptible to keloid formation, hyperpigmentation and hypertrophic scarring has not been established.

WHO SHOULD NOT USE EVOLENCE® COLLAGEN FILLER?

- Patients with a known allergy from eating any pork collagen product
- Patients with a history of severe or multiple occurring allergies.

People with these conditions, if they use **EVOLENCE®**, may have an allergic reaction and experience swelling, redness, or pain. In rare instances, allergic reactions to some materials can be severe and require medical assistance. Although no such reaction has ever been observed following use of **EVOLENCE®**, patients having experienced past allergic reactions to pork products should be aware of their medical history and these risks.

HOW DOES EVOLENCE® COLLAGEN FILLER WORK?

The production of collagen in the body decreases as you get older and/or exposed to the sun. The first visible signs of this decrease in production are the development of wrinkles. **EVOLENCE®** works by replacing and restoring collagen in the dermal layer of the skin where it naturally exists. **EVOLENCE®** will be injected with a fine needle midway or deep into your skin to help fill the areas of lost collagen where moderate to deep facial wrinkles and folds occur.

HOW IS EVOLENCE® COLLAGEN FILLER INJECTED?

EVOLENCE® is injected beneath the wrinkle or fold into the dermal layer of the skin using a fine needle.

DO INJECTIONS HURT?

Dermal fillers often require more than one injection during a treatment session to obtain an optimal result. The use of a needle to inject a product like a dermal filler can be associated with local skin discomfort. Certain areas of the face are more sensitive than others and your healthcare provider may choose either an external and/or local injectable anesthetic to help prevent discomfort and pain. Discuss pain management with your healthcare provider.

ARE THE RESULTS FROM EVOLENCE® COLLAGEN FILLER IMMEDIATE?

Yes. The natural collagen structure of **EVOLENCE®** fills the space of the depleted collagen and decreases the appearance of wrinkles, so it immediately gives the skin a smoother appearance.

HOW MANY TREATMENTS ARE REQUIRED?

One treatment with **EVOLENCE®** may be all that is required to achieve optimal wrinkle smoothing. The decision for additional treatments with **EVOLENCE®** is left up to you and your healthcare provider. Your healthcare provider will generally like to see you within two weeks of the first treatment to assess your satisfaction and to measure the success of treatment.

Following your initial treatment, you and your healthcare provider will determine when future injections are needed.

HOW LONG DOES EVOLENCE® COLLAGEN FILLER LAST?

The length of time that **EVOLENCE®** lasts in the body may vary from patient to patient. The duration may also depend on the amount of **EVOLENCE®** injected and the injected area. Information from a US clinical trial has shown that 76.5%

of the patients maintained the effects of **EVOLENCE®** for at least 12 months. Data gained from animal studies, foreign clinical studies and usage of **EVOLENCE®** in other countries have demonstrated that **EVOLENCE®** has lasted for up to 12 months.

WHAT CAN I EXPECT TO HAPPEN AT A TREATMENT SESSION?

- Your healthcare provider will answer any questions you have before your treatment.
- Remove all make-up prior to your treatment.
- An antiseptic will be used to clean all of the areas to be treated.
- Local anesthetics will be used if needed.
- Small amounts of **EVOLENCE®** will be injected into the skin.
- You will then receive instructions on how to care for the treated area once you leave the office.

WHAT CAN I EXPECT AFTER TREATMENT?

Immediately after your treatment, the injection sites may be painful and red or swollen. These site reactions are typically mild and go away with time, usually within hours to a few days. Follow the post-treatment directions given to you by your healthcare provider. If a side effect lasts longer than expected and is of concern to you, contact your healthcare provider. You might have a mild to moderate reaction at the injection site, but that should clear up in a few days.

You should follow these instructions.

- Within the first 24-48 hours you should avoid.
 - Strenuous exercise
 - Excessive sun, extreme heat, or extreme cold exposure
 - Alcoholic beverages

Exposure to any of the above may cause temporary redness, swelling, or itching at the injection site.

WHAT DID CLINICAL STUDIES SHOW?

EVOLENCE® collagen filler was studied in 149 patients who were injected with **EVOLENCE®** on one side of the mouth and a Hyaluronic Acid based filler on the other. The most common injection-related side effects include pain, redness, and swelling. The majority of these side effects (80%) were mild and disappeared within 1-7 days of injection. The percentage of the common injections site reactions are represented in the table below:

Injection Site Reactions (occurred in >5% of patients; # of patients =149)				
	EVOLENCE®		Restylane®	
	# of patients	% of patients	# of patients	% of patients
Total # of subjects	123	82.6	130	87.2
Injection site pain	84	56.4	95	63.8
Injection site redness (erythema)	86	57.8	89	59.7
Injection site swelling	80	53.7	102	68.5
Injection site bruising	54	36.2	71	47.7
Injection site itching (pruritus)	23	15.4	25	16.8
Injection site hardness (induration)	20	13.4	9	6.0

Other rare side effects of dermal fillers include the development of small lumps in the skin at the treated areas. While these lumps may not be visible and may go away with time, you or your doctor may notice them when the treated area is pressed upon.

As with any skin injection, there is a risk of infection.

Please report any side effect to your healthcare provider.

WHAT SHOULD I TELL MY HEALTHCARE PROVIDER ABOUT THE MEDICATIONS I TAKE?

Talk with your doctor about all medications that you are taking. In addition, discuss over-the-counter medications and natural products that you are using on a regular basis. It is also recommended that you tell your doctor about other fillers or procedures you have had in the past. If you are taking a blood thinner or medications that may interfere with clotting of the blood such as aspirin, Ibuprofen or Vitamin E products, you may be more likely to develop bruising at the sites of injection.

No formal drug interaction studies have been done with **EVOLENCE®**. Talk with your healthcare provider about your medical history prior to deciding on a specific treatment.

WHEN SHOULD I NOTIFY MY HEALTHCARE PROVIDER IF I HAVE CONCERNS?

Any side effect that lasts longer than a week should be reported to your healthcare provider. Call your healthcare provider if you are concerned about your side effect or think that you have a complication.

HOW QUICKLY CAN I GET BACK TO MY DAILY ACTIVITIES?

The majority of patients who receive **EVOLENCE®** collagen filler injections continue with their daily activities following treatment. However, during the first 24-48 hours after treatment, exposure to extremes of temperature (hot or cold) or strong sunlight should be avoided to reduce risk of inflammation. After this time you can go about your normal daily activities with no other treatment required.

**WHEN WILL I BE ABLE TO APPLY MAKE-UP AFTER EVOLENCE®
COLLAGEN FILLER INJECTIONS?**

Do not apply make-up immediately after treatment to avoid any complications and to keep the treated area clean. You should ask your healthcare provider when make-up may be applied after treatment.

WHAT OTHER TREATMENTS ARE AVAILABLE TO ME?

There are a variety of treatments and/or dermal fillers available in the United States. Safety and effectiveness vary. You should consult with your healthcare provider to determine which one is right for you.

For further questions and information, or to report an adverse reaction, please call 1-800-386-5362

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