EVOLYSSE™
FORM

Patient Information

About EVOLYSSE™ FORM

Before beginning your treatments, please review this important information.

1. GLOSSARY

Terms in the glossary are bold throughout the document.

Anesthetic – A substance that reduces sensitivity to pain.
Cold-X™ Technology – An innovative manufacturing process aimed at preserving the natural structure of the HA molecule, for long-lasting, natural-looking results.
Dynamic – Able to move, not fixed in place, such as the skin on the face**.**
Hyaluronic acid (HA) – A polysaccharide (sugar) that is naturally found in the body. HA hydrates the skin to help maintain its flexibility and elasticity. EVOLYSSE™ FORM is made from a modified form of the HA that is naturally found in your body.
Hyaluronidase – An enzyme that dissolves HA.
Lidocaine – A synthetic compound used as a local **anesthetic** to decrease pain.
Nasolabial folds (NLFs) – The medical term for the wrinkles and fold lines between the nose and the corners of the mouth, commonly referred to as 'laugh lines' or 'smile lines'.
Pigmentation disorders – General term to refer to health conditions that affect skin color.
Retreatment – An additional treatment with EVOLYSSE™ FORM that is given after the effects of the initial treatment start to wear off to maintain the desired aesthetic outcome.
Topical – A cream or ointment applied to the skin only affecting the area applied.
Touch-up – An additional injection with a small amount of EVOLYSSE™ FORM usually given 2 weeks after the initial injection. A **touch-up** treatment may be necessary to achieve the desired aesthetic outcome.

2. PRODUCT DESCRIPTION

What is it?
EVOLYSSE™ FORM is an injectable gel (dermal filler) made of **hyaluronic acid (HA)**, a natural occurring sugar found in the body, and a small amount of **lidocaine**. EVOLYSSE™ FORM is injected in the skin to smooth wrinkles that form in dynamic areas of the face, especially between the nose and corners of the mouth (**NLFs**). It is approved for use in adults over 22 years of age.

EVOLYSSE™ FORM is produced using **COLD-X™ Technology**, an advanced manufacturing process aimed at preserving the natural HA structure. The HA of the gel is made from a non-animal source. EVOLYSSE™ FORM contains a small amount of an aesthetic medicine (**lidocaine**), to help reduce discomfort during injection

How does it work?
Facial wrinkles may develop over time for many reasons, for example, due to the natural aging process or after weight loss. EVOLYSSE™ FORM is designed to plump the skin by temporarily filling and reducing the appearance of **dynamic** facial lines, such as the lines that form around your mouth. EVOLYSSE™ FORM is injected into facial wrinkles using a fine gauge needle to restore a

smoother appearance. The **lidocaine** in the gel improves the comfort of the injection by easing sensitivity to pain.

3. CONTRAINDICATIONS

Are there any reasons why I should not receive treatment with EVOLYSSE™ FORM?
Your doctor will ask about your medical history to determine if treatment with EVOLYSSE™ FORM is right for you. You should not use EVOLYSSE™ FORM if:

- You have severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies.
- You have a history of allergies to Gram-positive bacterial proteins (EVOLYSSE™ FORM contains trace amounts this material).
- You have a history of allergies to **lidocaine** (EVOLYSSE™ FORM contains **lidocaine**).

4. PRECAUTIONS

What precautions should my doctor advise me about?
The following are important treatment considerations for you to discuss with your doctor and understand to help avoid unsatisfactory results and complications:

- Minimize exposure to extreme heat or cold as doing so may cause temporary redness, swelling, and/or itching at the injection site.
- Tell your doctor if you are using any medication that can prolong bleeding, such as aspirin, ibuprofen, or other blood thinners. As with any injection, this may increase bruising or bleeding at the injection site.
- Tell your doctor if you are planning laser treatment, chemical peel, or any other procedure after treatment with EVOLYSSE™ FORM as there is a possible risk of an inflammatory reaction at the treatment site.
- Tell your doctor which areas of your face you would like to have treated. EVOLYSSE™ FORM is intended for **dynamic** wrinkles and folds such as **NLFs**. The safety and effectiveness for other treatment areas have not been established in controlled, clinical studies.
- Tell your doctor if you are on therapy used to decrease your immune response. Use may result in an increased risk of infection.
- Tell your doctor if you are pregnant or breastfeeding. The safety for use during pregnancy or in women who are breastfeeding has not been studied.
- Tell your doctor if you have a history of excessive scarring (thick, hard scars). The safety of EVOLYSSE™ FORM in patients with a history of excessive scarring has not been studied and may result in additional scars.
- Tell your doctor if you have a history of **pigmentation disorders**. The safety of EVOLYSSE™ FORM in patients with a history of **pigmentation disorders** has not been studied. Use in these patients may result in pigmentation changes.
- Tell your doctor if you have a history of cold sores. Any injections, including EVOLYSSE™ FORM, around the mouth may trigger a recurrence of your cold sores.
- The use of EVOLYSSE™ FORM where skin sores, pimples, rashes, hives, cysts, or infections are present should be postponed until healing is complete. Use of EVOLYSSE™ FORM where these are present could delay healing or make your skin problems worse.

5. CLINICAL STUDY

How was the product studied?
EVOLYSSE™ FORM was tested in a clinical study of 70 subjects to establish the safety and effectiveness for reducing the appearance of wrinkles and folds. Participants were injected with EVOLYSSE™ FORM in 1 **NLF** and a different soft tissue filler (control) in the opposite **NLF**. To achieve the desired results, a **touch-up** treatment was allowed 2 weeks after the initial treatment. Participants could also receive a **retreatment** after 12 months to maintain the cosmetic effect.

To evaluate the safety of EVOLYSSE™ FORM, participants noted common side effects in daily diaries. Side effects were also reported by doctors during office visits with each participant. These office visits included discussing any symptoms or complaints with the participants and assessing the appearance of their **NLFs**. To evaluate the effectiveness of the product, study doctors used a 5-point Wrinkle Assessment Scale to score **NLF** severity. Participants also used questionnaires to rate aesthetic improvement and satisfaction with the appearance of their **NLFs** after treatment.

6. BENEFITS

What will it accomplish?
EVOLYSSE™ FORM injectable gel reduces the appearance of **dynamic** facial wrinkles, such as the lines that form around your mouth.

What did the clinical study show?
EVOLYSSE™ FORM was found to effectively reduce the appearance of moderate to severe **dynamic** facial wrinkles and folds. The clinical study showed that the improvement lasts for 12 months in most participants (72%). Study doctors reported:

- When assessed by photographs, 45% of participants showed a 1-point or greater improvement in **NLF** severity at 6 months after treatment
- When assessed in-person, 92% of participants had a 1-point or greater improvement in **NLF** severity at 6 months after treatment
- 83% of participants maintained at least a 1-point improvement through 9 months after treatment
- 72% of participants maintained at least a 1-point improvement through 12 months after treatment

Participants reported satisfaction with their **NLFs** throughout the study.

- 80% of participants rated their **NLFs** as improved 1-year after treatment,
- 88% would receive treatment again
- 85% would recommend treatment to a friend

7. RISKS

What side effects were seen in the clinical study?
Daily diaries were completed by 66 participants after treatment to document common side effects. Most participants (92% or 61 out of 66 participants) experienced a common side effect. Some participants experienced more than one. Table 1 gives the likelihood of experiencing a common

side effect, based on study results. Most side effects were mild and went away on their own within 1 week.

Table 1: Common Side Effects Observed in the Clinical Study

Side Effect	Likelihood of Experiencing a Side Effect
Tenderness	76% (76 out of 100 people)
Swelling	70% (70 out of 100 people)
Bruising	61% (61 out of 100 people)
Redness	58% (58 out of 100 people)
Lumps	58% (58 out of 100 people)
Pain	53% (53 out of 100 people)
Discoloration	36% (36 out of 100 people)
Itching	29% (29 out of 100 people)
Headache	6% (6 out of 100 people)

What adverse events were seen in the clinical study?
Adverse events were any side effects that lasted longer than the daily diary or were reported by doctors at any time throughout the study. Eleven participants experienced adverse events, which included injection site mass (lump/bump), discoloration, pain, redness, swelling, facial discomfort, bruising, feeling the product under their skin, headache, and skin swelling. Most events were mild and went away on their own within 60 days.

After **retreatment**, 2 participants experienced 2 adverse events including injection site pain and headache. Both events were mild and went away on their own.

What are other possible adverse events?
As with all injection procedures, there is a risk of infection.

One of the risks with using this product is the unintentional injection into a blood vessel. The chances of this happening are very small, but if it does happen, the complications can be serious, and may be permanent. These complications, which have been reported for facial injections, can include vision abnormalities, blindness, stroke, temporary scabs, or permanent scarring of the skin.

Although most side effects will resolve within 1 week, some may last longer. Your doctor may choose to treat them with medications, such as antibiotics, steroids, or **hyaluronidase**.

8. PROCEDURE INFORMATION

What happens in the office before the injection?
Each doctor may have a unique process for assessing and treating patients. The following is an example of a typical procedure that you may experience. Before the injection procedure, your doctor will ask you questions about your medical history as well as your treatment goals. Your doctor will discuss whether you are an appropriate candidate for EVOLYSSE™ FORM and review what to expect during and after treatment, including possible side effects. Your doctor will also

examine your facial skin and may take photos. Different options for pain management will be discussed, and if pretreatment numbing is desired, a **topical** such as **lidocaine** cream, or another **anesthetic** agent may be used. The treatment area will be cleaned and then prepared with alcohol or another antiseptic. Your doctor may use a pen to mark your face, identifying the planned areas of injection.

9. PROCEDURE DESCRIPTION

What happens during the procedure?
After the first injection, your doctor will wait a few seconds to allow the **lidocaine** to take effect before moving forward with the rest of the treatment. EVOLYSSE™ FORM will be injected in small amounts into the treatment area until the desired aesthetic outcome is achieved. Your doctor may massage the treatment area gently to ensure that the product integrates in the skin and is evenly distributed for a smooth appearance. Ice may be applied for a brief period following treatment to minimize swelling and reduce pain.

Do the injections hurt?
Injections may cause some discomfort during and after the procedure. In the EVOLYSSE™ FORM clinical study. In the EVOLYSSE™ FORM clinical study, participants rated the pain score of 3 on a scale where 0 is no pain and 10 is worst pain imaginable. EVOLYSSE™ FORM has **lidocaine** to reduce injection site pain. Your doctor may also choose to numb the treatment area with a **topical** or injected numbing agent to further minimize discomfort.

10. AFTER PROCEDURE INFORMATION

What should I expect after the procedure?
In the EVOLYSSE™ FORM clinical study, the most common side effects were temporary side effects at the treatment site such as tenderness, swelling, bruising, redness, and lumps.

Your doctor will also tell you what to expect following EVOLYSSE™ FORM treatment. Within the first 24 hours, you should minimize exposure of the treated area to extreme temperatures (e.g., intense cold or sauna) until local inflammation has resolved.

Will I need more than one treatment to achieve my desired results?
You should discuss your treatment goals and plan with your doctor. The regime with EVOLYSSE™ FORM may require multiple treatments to achieve the desire results. In the EVOLYSSE™ FORM clinical study, 73% (51 out of 70 participants) received a **touch-up** treatment 2 weeks after initial treatment to achieve the desired aesthetic outcome.

Do the results last forever?
No. While individual results may vary, in the clinical study, the results lasted for 12 months in most participants. **Retreatment** is usually needed to maintain your desired result.

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11. WHEN TO CALL YOUR DOCTOR

When should I call my doctor?
Call your doctor immediately if you have:

1) Changes in your vision
2) Signs of a stroke (including sudden difficulty speaking, numbness or weakness in your face, arms or legs, difficulty walking, face drooping, severe headache, dizziness, or confusion)
3) White appearance of the skin
4) Unusual pain during or shortly after treatment

Be sure to call your doctor if you have:

1) Significant pain away from the injection site
2) Any redness and/or visible swelling that lasts for more than a few days
3) Any side effect that occurs weeks or months after treatment
4) Any other symptoms that cause you concern

12. ADDITIONAL INFORMATION

If you have any questions about EVOLYSSE™ FORM, please contact Evolus Customer Experience at 877-386-5871.

www.evolus.com

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