

MERZ AESTHETICS®

RADIESSE®

RADIESSE® Dermal Filler for the
Correction of Moderate to Severe
Facial Wrinkles and Folds, such as
Nasolabial Folds

PATIENT INFORMATION GUIDE

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This guide will help you decide whether treatment with RADIESSE® is right for you. This information does not take the place of discussion with your doctor. This guide will answer some questions you may have about RADIESSE® treatment.

- Only you and your doctor can decide whether RADIESSE® is right for you. Other treatments are available to correct wrinkles and folds and you may discuss these treatment options with your doctor.
- Please read all the information in this guide and discuss any questions with your doctor before you are treated with RADIESSE®.

Keep this information. You may want to read it again.

GLOSSARY

Anesthetic

A substance that reduces sensitivity to pain.

Calcium Hydroxylapatite (CaHA)

A substance that is naturally in the body. CaHA is part of what makes up bone and teeth. The CaHA found in RADIESSE® is a man-made form of the CaHA found in the body.

Dermal filler

A substance that is injected in the skin to create a smoother and/or fuller appearance in the face.

Microspheres

Round particles of CaHA smaller than a grain of salt.

Opaque

Not able to be seen through, not transparent or clear.

Topical

A cream or ointment applied on top of the skin and affecting only the area to which it is applied.

Touch-up

An additional injection of a small amount of dermal filler usually given about 2 weeks to 1 month after the first injection. A touch-up treatment may be needed to get the desired cosmetic result.

Vascular compromise

A situation where there is a decrease of blood flow through the vessels.

(Note: The terms in the glossary are underlined throughout this document)

ABOUT RADIESSE®

What is RADIESSE®?

RADIESSE® is an opaque, white colored dermal filler made up of CaHA microspheres in a water based gel injected into the skin of the face to smooth away wrinkles such as the lines from your nose to the corners of your mouth (nasolabial folds). RADIESSE® is non-animal based and free from animal protein. Before you are injected, you do not have to be tested to see if you are allergic to RADIESSE®.

What is RADIESSE® used for?

RADIESSE® is injected into your skin to smooth away wrinkles and folds, such as the lines from your nose to the corners of your mouth (nasolabial folds).

How does it work?

RADIESSE® is injected into the skin with a thin needle to plump the skin and add volume to smooth facial wrinkles and folds such as the lines from your nose to the corners of your mouth.

Your doctor will inject the product into your skin to make the wrinkles shallower and smoother. RADIESSE® will not correct the underlying causes of wrinkles and folds.

SAFETY INFORMATION

Are there any reasons why I should not receive RADIESSE®?

Your doctor will ask about your medical history to determine if you are a good candidate for injection of RADIESSE®. In order to avoid complications and unsatisfactory results, RADIESSE® should not be used if:

- You have severe allergies marked by a history of severe reaction (anaphylaxis) or history or presence of severe allergies. Use may result in an allergic reaction.
- You have had a severe reaction (hypersensitivity) to any of the components (CaHA, sterile water, carboxymethylcellulose, glycerin). Use may result in an allergic reaction.
- You have a bleeding disorder.

What are some Warnings to consider?

It is important to share your medical information with your doctor. Together you can make an informed decision as to whether or not RADIESSE® is right for you. Because use could result in significant injury, RADIESSE® should not be used in the following cases:

- Warning: One of the risks of using RADIESSE® is 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. If you have changes in your vision, 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), white appearance of the skin or unusual pain during or shortly after treatment, you should notify your health care practitioner immediately.

- RADIESSE® should not be used in any person with active skin inflammation or infection in or near the treatment area until the inflammation or infection has been controlled.
- The safety and effectiveness of RADIESSE® for use in the lips has not been established. Use in the lips may result in unsatisfactory results and injury such as the formation of nodules (small lumps of dermal filler material).
- Injection procedure reactions have been observed consisting mainly of short-term (i.e. < 7 days) bruising, redness and swelling.

What precautions should my doctor tell me about?

The following are important treatment considerations for you to discuss with your doctor and understand in order to help avoid unsatisfactory results and complications.

- You should limit the exposure of the treated area to sun or heat exposure for 24 hours after treatment or until any initial swelling and redness has resolved.
- The [CaHA microspheres](#) of RADIESSE® are visible on CT scans and may be visible in standard, plain radiography. Tell your doctor, as well as your radiologists, that you have had RADIESSE® injected into your face so they are aware it is present when they are looking at your CT scans or X-rays.
- Tell your doctor if you are pregnant or breast-feeding. The safety of RADIESSE® for use during pregnancy, or in women who are breast-feeding has not been established.
- The safety of RADIESSE® in patients under 18 years has not been established.
- Tell your doctor about medicines you are taking because patients who are using medications that can prolong bleeding, such as aspirin or warfarin, may, as with any injection, experience increased bruising or bleeding at the injection site.
- Tell your doctor if you have a history of herpes. Injection of RADIESSE® into patients with a history of herpes can activate herpes.

- Tell your doctor if you have had dermal therapies such as epilation, UV irradiation, or laser, mechanical or chemical peeling procedures. The safety of RADIESSE® with these procedures has not been evaluated in controlled clinical trials.
- Safety and effectiveness in the area around the eyes (periorbital) and the lips have not been established
- No studies on the interactions of RADIESSE® with drugs or other substances or implants have been conducted.

What are possible side effects?

In the clinical study of RADIESSE®, most side effects were mild in nature (uncomfortable). The most common side effects are swelling, redness, pain, bruising and itching. These side effects are also seen with other facial injection procedures.

- RADIESSE® injection carries a risk of infection
- If laser treatment, chemical peeling, or any other procedure based on active dermal response is considered after treatment with RADIESSE®, swelling may occur at the implant site. This also applies if you receive RADIESSE® injection before the skin has healed after a laser or chemical peel.
- You may be able to feel the RADIESSE® material in your skin for some time after your treatment. It may feel firm if you touch the area that was injected. This feeling will go away over the next several weeks.

Have there been adverse events reported through post-market surveillance?

The following adverse events have been identified during post-approval use of RADIESSE®. Because they are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to RADIESSE®. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to RADIESSE®: (skin) infection, loss of aesthetic effect, product displacement/migration, allergic reaction including serious reaction, hives, rash, itch, superficial and deep skin swelling, inflammation, tissue damage, nodules, skin hardening, redness, skin discoloration, pustule, hair loss, tingling, drooping of the upper eyelid, pain, headache, asymmetry (treatment area), abscess, herpetic infection including herpes simplex and herpes zoster, bruising, blanching, blistering, dizziness, festoons, flu-like symptoms, muscular weakness or tingling, rapid breathing, decreased blood flow, swelling of lymph tissue, nausea, swelling of the tissue surrounding the heart, scarring, sensitivity to cold, blocking/narrowing of blood vessels including in the eye, double vision, visual impairment/blindness, facial muscle paralysis.

Based on information reported to Merz about the use of RADIESSE®, your physician may recommend additional interventions after RADIESSE®: antibiotics, anti-inflammatories, corticosteroids, anti-histamines, analgesics, massage, warm compress, excision, drainage, and surgery. This information does not constitute and is not intended to be medical advice, a recommendation on how to treat an adverse event or an exclusive list of possible interventions. Your physician should always evaluate each individual case, and independently determine what treatment(s), if any, are right for you.

BENEFITS of RADIESSE®

What will RADIESSE® accomplish?

It will temporarily provide volume in facial wrinkles and folds such as the line from your nose to the corners of your mouth and will provide a smoother contour and more youthful appearance to the face.

How long do treatment effects last?

Although treatment effects will differ from person to person. In a clinical study of 117 patients 78.6% (about 91 out of 117 patients) showed improvement in their facial wrinkles and folds 6 months after treatment with RADIESSE® dermal filler. Thirty-five of these patients continued to show improvement at least 30 months after their last injection.

What are some benefits from the RADIESSE® clinical study?

RADIESSE® was shown to improve the appearance of face by reducing folds and wrinkles in the skin as reported by patients and doctors.

Reduction of folds in the face one week after treatment.



BEFORE TREATMENT



ONE WEEK AFTER TREATMENT*

*Individual results may vary

ABOUT THE PROCEDURE

Do the injections hurt?

Injection may cause some discomfort during and after the procedure. You and your doctor may decide to numb the treatment area with a topical or injected anesthetic to further reduce your discomfort.

What can I expect to happen at a treatment session?

Note that each doctor may have a different process for assessing and treating patients. The following is an example of what you would experience with a typical procedure:

Before treatment:

- Your doctor will answer all your questions and prepare you for the treatment. You can use the space at the end of this guide to write down your questions before you see your doctor.
- Your doctor will ask you questions about your medical history.
- Your doctor will clean the area where the injections will be given.
- You and your doctor will determine if a topical or local anesthetic is needed.

During treatment:

- Your doctor will inject a small amount of RADIESE® into the skin using a thin needle until you have received the desired correction.
- Your doctor may gently message the treatment area to ensure the product is evenly distributed.

After treatment:

- Your doctor may periodically apply an ice pack to the treatment area to help reduce swelling.
- Your health care provider will give you specific after treatment care instructions.

How many treatments are required to get the look I want?

The number of treatments required to get the look you want depends on your face and your personal treatment plan. Your doctor will decide with you the number of treatment sessions you will need and the amount of RADIESE® you will need at each treatment session. A touch-up treatment may be required to get the desired outcome.

