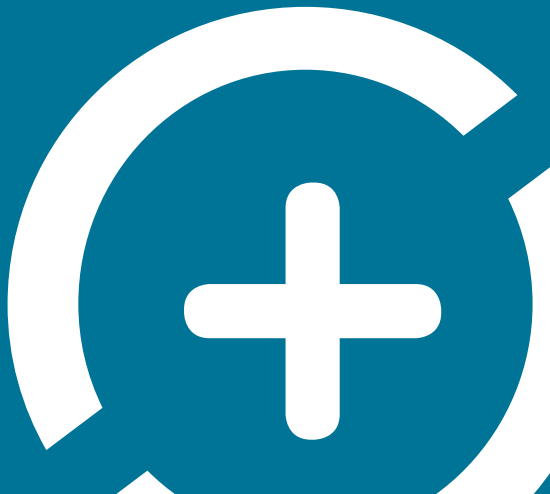
MERZ AESTHETICS®

RADIESSE®

Lidocaine

PATIENT INFORMATION GUIDE



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This guide will help you decide whether treatment with RADIESSE® (+) Lidocaine (hereinafter referred to as RADIESSE® (+)) is right for you. This information does not take the place of a 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 naturally in your body.

Contour

An outline that represents the shape or form of something.

Dermal filler

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

Lidocaine

A man-made compound used as a local anesthetic to decrease pain

Microspheres

Round particles of CaHA smaller than grains 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 is it 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 blood vessels

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

ABOUT RADIESSE® (+)

What is RADIESSE® (+)?

RADIESSE® (+) is an opaque dermal filler that contains a small quantity of local anesthetic (lidocaine). The product is made up of CaHA microspheres in a water-based gel. RADIESSE® (+) is non animal based and free from animal protein. Allergy pre-testing is not required. RADIESSE® (+) is injected into the skin of the face to smooth away wrinkles and folds such as the lines from your nose to the corners of your mouth (nasolabial folds). RADIESSE® (+) may also be injected in lower part of your face to improve the contour of your jawline. The addition of lidocaine helps to improve the comfort of the injection.

Why add Lidocaine to RADIESSE®?

Lidocaine was added to reduce the pain and discomfort during and after injection. In a clinical study, RADIESSE® (+) was shown to have an effect on reducing pain.

In the clinical study, 101 patients received RADIESSE® on one side of the face and RADIESSE® (+) on the other side of the face. Patients rated their pain on a scale of 0 to 10. On the scale, 0 was no pain and 10 was very severe pain. Immediately after injection, patients rated their pain about 6.7 on a scale of 0 to 10 for the side of the face injected with RADIESSE® compared to about 2.3 on the same scale for the side of the face treated with RADIESSE® (+).

Sixty (60) minutes after treatment, patients rated their pain about 1.1 on a scale of 0 to 10 for the side of the face injected with RADIESSE® compared to about 0.3 on the same scale for the side of the face treated with RADIESSE® (+).

What is RADIESSE® (+) used for?

RADIESSE® (+) can be 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).

RADIESSE® (+) can be injected into your skin to improve the contour of your jawline.

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, or to improve the contour of your jawline. For wrinkles, your doctor will inject the product into your skin to make it shallower and smoother. Your doctor will inject the product into your skin of your jawline to add volume and make it more defined. RADIESSE® (+) will not correct the underlying causes of wrinkles and folds, or lack of jawline contour.

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

What are some Warnings to consider?

It is important that you share your medical information with your doctor. Together, you can make an informed decision as to whether 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 with 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 inflammatory 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.
- RADIESSE® (+) must not be injected into blood vessels. Local tissue damage and/or scarring may occur after injection in or near blood vessels. This is thought to result from injury or blockage of blood vessels.

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 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 in your face so that 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 breastfeeding. The safety of RADIESSE® (+) for use during pregnancy, or in women who are breastfeeding has not been established.
- The safety of RADIESSE® (+) in patients under 18 years has not been established.
- Tell your doctor about all the 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 excessive scarring (thick, hard scars). The safety of RADIESSE® (+) in patients with increased susceptibility to keloid formation and hypertrophic scarring has not been studied.
- 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 in the lips have not been established.
- No studies of 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. In the clinical study of RADIESSE® (+) for use in the jawline, the duration of most side effects was 7 days or less (57%), 8-14 days (26%), or 15-28 days (17%).

- 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 a RADIESSE® (+) injection before the skin has healed after a laser treatment 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 several weeks.
- Rarely, vision abnormalities have been reported after treatment with RADIESSE® and other dermal fillers.
- No studies of interactions of RADIESSE® (+) with drugs or other substances or implants have been conducted.

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 with or without fluid or pus (including pustule or abscess), loss of aesthetic effect, product displacement/migration from injection site, minor or serious, allergic reactions including that could also involve hives, rash, itch, superficial or 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 (cold sores) and herpes zoster (shingles), bruising, blanching (skin turning pale), blistering, dizziness, festoons (swelling or loose skin appearance under the eye), flu-like symptoms, muscular weakness or tingling, rapid breathing, decreased blood flow, swelling of lymph nodes, nausea, swelling of the tissue surrounding the heart, scarring at treatment area, sensitivity to cold, blocking/narrowing of blood vessels including in the eye, double vision, visual impairment/blindness, and facial muscle paralysis.

Delayed-onset inflammation near the site of dermal filler injections is one of the known adverse events associated with dermal fillers. Cases of delayed-onset inflammation have been reported to occur at the dermal filler treatment site following viral or bacterial illnesses or infections, vaccinations, or dental procedures. Typically, the reported inflammation was responsive to treatment or resolved on its own.

Based on information reported to Merz about the use of RADIESSE®, your physician may recommend additional treatments after RADIESSE®: drugs such as antibiotics, anti-inflammatories, corticosteroids or other anti-inflammatories, anti-histamines, pain medications, or analgesics, and treatment such as 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 treatments(s), if any, are right for you.

BENEFITS of RADIESSE® (+)

What will RADIESSE® (+) accomplish?

It will temporarily correct volume in facial wrinkles and folds such as the lines from your nose to the corners of your mouth or your jawline and will provide a smoother contour and more youthful appearance to the face. The lidocaine in the product will reduce the pain and discomfort during and after injection.

How long do treatment effects last?

Although treatment effects will differ for each person, in a clinical study of 117 patients 78.6% of the patients (about 91 of the 117 patients) showed improvement in their facial wrinkles and folds 6 months after treatment with RADIESSE® Dermal Filler. Thirty-five (35) of these patients continued to show improvement at least 30 months and up to 39 months after their last injection.

In a clinical study, 75.6% (or 93/123) treated patients showed improvement in the contour of their jawline 12 weeks after treatment with RADIESSE® Dermal Filler. About 67.3% (76/113) of patients continued to see those improvements for up to 48 weeks after treatment. The 113 patients correspond to those patients that had a response 12 weeks after treatment and that also had effectiveness assessment data 48 weeks after treatment.

Has RADIESSE® (+) been studied?

In a clinical study, RADIESSE® (+) was shown to have an effect on reducing pain. In the clinical study, 101 patients received RADIESSE® on one side of the face and RADIESSE® (+) on the other side of the face. Patients rated their pain on a scale of 0 to 10. On the scale, 0 was no pain and 10 was very severe pain. Immediately after injection, patients rated their pain about 6.7 on a scale of 0 to 10 for the side of the face injected with RADIESSE® compared to about 2.3 on the same scale for the side of the face treated with RADIESSE® (+).

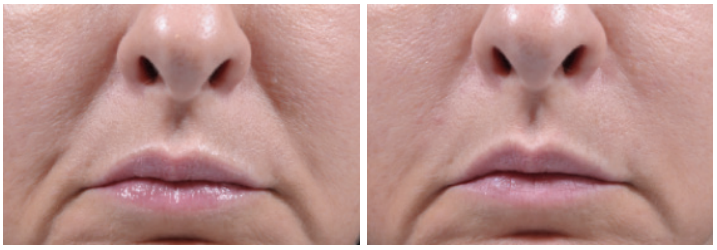
Sixty (60) minutes after treatment, patients rated their pain about 1.1 on a scale of 0 to 10 for the side of the face injected with RADIESSE® compared to about 0.3 on the same scale for the side of the face treated with RADIESSE® (+).

In another clinical study RADIESSE® (+) was shown to improve the contour of the jawline. In this clinical study 75.6% (or 93/123) treated patients showed improvement in the contour of their jawline 12 weeks after treatment. Study doctors and the patients evaluated the overall appearance of the jawline and rated the changes. Study doctors reported that they could see improvements in the contour of the jawline in 99.1% (or 115/116) treated patients. The majority of subjects 94.0% (or 109/116) self reported an improvement in the appearance of their jawline. Subjects also reported that they were satisfied with how prominent, sculpted, nice, and smooth their jaw looked and with the profile of their jawline after treatment.

What are some benefits from the RADIESSE® (+) clinical study?

RADIESSE® (+) was shown to have an effect on reducing the pain related to the injection. Other benefits included improved appearance of the face by reducing folds and wrinkles in the skin, and the contour of the jawline as reported by both 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?

Injections may cause some discomfort during and after the procedure. RADIESSE® (+) contains lidocaine which has been shown to reduce pain. You and your doctor may also 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 of 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 small amounts of RADIESSE® (+) into the skin using a thin needle until you have received the desired correction.
- Your doctor may gently massage 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 RADIESSE® (+) you will need at each treatment session. A touch-up treatment may be required to get the desired outcome.

ADDITIONAL INFORMATION

What should I do if I have a problem after a RADIESSE® (+) treatment? When should I call my doctor?

If you believe that you have experienced a serious problem related to your RADIESSE® (+) treatment, you should call your doctor. You may also call Merz North America during normal business hours at 1-844-469-6379 to report any side effects.

What should I do if I have additional questions?

For further questions and information, please call Merz North America at 1-844-469-6379.

QUESTIONS FOR MY DOCTOR

MERZ AESTHETICS®

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