MERZ AESTHETICS®

RADIESSE®

RADIESSE® Dermal Filler for the Restoration and/or Correction of the Signs of Facial Fat Loss in People with Human Immunodeficiency Virus

PATIENT INFORMATION GUIDE

Table of Contents

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.
- 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.

Facial Lipoatrophy

The loss of facial fat.

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.

HIV

Human Immunodeficiency Virus.

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 correct facial fat loss associated with human immunodeficiency virus. 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 for soft tissue augmentation and restoration of the face to correct facial lipoatrophy (lost facial fat) associated with HIV infection.

How does it work?

RADIESSE® is injected below the surface of the skin in the area of fat loss. RADIESSE® results in aesthetic improvement and provides an increase in cheek thickness in the treated area. Visible results appear at the first treatment session. RADIESSE® will not correct the underlying cause of the facial lipoatrophy but will improve appearance in the treated area.

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 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, you should understand these risks:

- 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 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 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 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 redness, bruising, and swelling. 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 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.

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 treatments(s), if any, are right for you.

BENEFITS of RADIESSE®

What will RADIESSE® accomplish?

RADIESSE® results in aesthetic improvement and provides an increase in cheek thickness in the treated area. Visible results are present immediately, i.e. first treatment session.

How long do treatment effects last?

Although treatment effects will differ for each person, in a clinical study 90.1% (about 81 out of 91 patients) patients reported improvement 30 months after initial treatment.

What are some benefits from the RADIESSE® clinical study?

RADIESSE® was shown to result in aesthetic improvement and provide an increase in cheek thickness in the treated area.

ABOUT THE PROCEDURE

Do the injections hurt?

Injections may cause some discomfort during and after the procedure. 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 facial characteristics 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 1-866-862-1211 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 1-866-862-1211.

QUESTIONS FOR MY DOCTOR

MERZ AESTHETICS®

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