

A PATIENT'S GUIDE

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



- ◆ Read all the information before you are treated.
- ◆ Keep this information. You may want to refer to it again.
- ◆ If you have any questions, please ask your doctor.

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INTRODUCTION

This information will help you decide whether treatment with Radiesse is right for you. This information does not take the place of a discussion with your doctor but will answer some questions about treatment with Radiesse.

Please read this information and discuss any questions with your doctor. Only you and your doctor can decide whether Radiesse is right for you.

GLOSSARY

Anesthetic:

A substance that causes loss of feeling or awareness. A topical or local anesthetic causes temporary loss of feeling in a part of the body, and may make your treatment more comfortable.

Facial Lipoatrophy:

The loss of facial fat.

Calcium Hydroxylapatite:

Calcium hydroxylapatite is a biocompatible, biodegradable material that is similar to one of the components commonly found in natural bone. Calcium hydroxylapatite has been widely used for many years in medical products.

Side effect:

An undesirable event caused by use of the product.

BACKGROUND INFORMATION

What is Radiesse?

Radiesse is an injectable for treating facial fat loss associated with human immunodeficiency virus. Calcium Hydroxylapatite has a history of safe use in otology (ears), laryngeal (vocal chords), and dental and orthopedic applications (see glossary).

Who might benefit from treatment with Radiesse?

Radiesse is intended for soft tissue augmentation and restoration of the face to correct facial lipoatrophy (lost facial fat).

Who should not use Radiesse?

Talk to your doctor about your medical history when deciding on treatment options. You should not use Radiesse if you are allergic to any ingredient of Radiesse. You may also not choose Radiesse if you desire only a short-term augmentation or restoration.

Are skin tests needed before treatment with Radiesse?

No skin testing is required prior to use.

How does Radiesse 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.

How many treatments are required?

Your doctor will decide with you the number of treatment sessions and the amount of Radiesse you will need at each treatment session. Generally, significant augmentation or restoration may be achieved in a first treatment. A touch-up may be required to achieve optimal results, and periodic future touch-up treatments may be needed to maintain the augmentation or restoration.

How often are treatments given?

Your doctor will decide how often treatments are given based upon your needs and desires and the areas and volume of treatment required.

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How long do treatment effects last?

Treatment effects will differ for each person. In a clinical study, the treatment lasted for 1 year after the first treatment session in all patients.

Do injections of Radiesse hurt?

As with any injection, injections with Radiesse may hurt. Radiesse is injected in small amounts using a very fine needle. Your doctor may apply a topical or local anesthetic.

What can I expect to happen at a treatment session?

- Your doctor will answer all of your questions and prepare you for the treatment.
- The area where the injections will be given will be cleaned with an antiseptic.
- You and your doctor will determine if an anesthetic is needed.
- Radiesse will be injected in small amounts into the skin using a very fine needle.
- An ice pack may be applied to the treatment area before or after treatment to help reduce swelling.

What are the possible side effects of treatment with Radiesse?

Talk to your doctor about the possible side effects of Radiesse. The most common are redness, bruising, or swelling. These generally last for a short time and are mild in nature. As with all procedures that involve an injection through the skin, there is a risk of infection. However, no infections have been reported in the clinical study of Radiesse. Report any side effects you may experience to your doctor. The table below shows the side effects seen in a clinical study of 100 patients. Most of the side effects were seen at the time of the Radiesse injection, which is common for facial injection procedures (see Tables 1-4).

Table 1. Most Severe Side Effects Reported Through Patient Diaries

Adverse Event	Total Reporting Symptoms	Mild N(%)	Moderate N(%)	Severe N(%)
Bruising	64	34 (53.1)	25 (39.1)	5 (7.8)
Swelling	99	46 (46.5)	49 (49.5)	4 (4.0)
Redness	55	32 (58.2)	23 (41.8)	0 (0.0)
Granuloma	0	0 (0.0)	0 (0.0)	0 (0.0)
Nodule	0	0 (0.0)	0 (0.0)	0 (0.0)
Pain	37	24 (64.9)	13 (35.1)	0 (0.0)
Itching	21	18 (85.7)	3 (14.3)	0 (0.0)
Other	43	27 (62.8)	15 (34.9)	1 (2.3)

Table 2. Most Severe Side Effects Reported Through Other Methods

Adverse Event	Total Reporting Symptoms	Mild N(%)	Moderate N(%)	Severe N(%)
Bruising	3	2 (66.7)	1 (33.3)	0 (0.0)
Swelling	8	8 (100.0)	0 (0.0)	0 (0.0)
Redness	3	3 (100.0)	0 (0.0)	0 (0.0)
Granuloma	0	0 (0.0)	0 (0.0)	0 (0.0)
Nodule	0	0 (0.0)	0 (0.0)	0 (0.0)
Pain	2	1 (50.0)	0 (0.0)	1 (50.0)
Itching	0	0 (0.0)	0 (0.0)	0 (0.0)
Other	26	20 (76.9)	6 (23.1)	0 (0.0)

Table 3. Length of Time for Side Effects Reported Through Patient Diaries

	Total Reporting Symptoms	Number of Days			
		1-3 N(%)	4-7 N(%)	8-14 N(%)	>14 N(%)
Bruising	142	29 (20.4%)	51 (35.9%)	50 (35.2%)	12 (8.5%)
Swelling	430	205 (47.7%)	153 (35.6%)	52 (12.1%)	20 (4.7%)
Redness	210	114 (54.3%)	69 (32.9%)	22 (10.5%)	5 (2.4%)
Pain	110	54 (49.1%)	32 (29.1%)	18 (16.4%)	6 (5.5%)
Itching	54	28 (51.9%)	9 (16.7%)	6 (11.1%)	11 (20.4%)
Other	112	40 (35.7%)	19 (17.0%)	18 (16.1%)	35 (31.3%)

Table 4. Length of Time for Side Effects Reported Through Other Methods

	Total Reporting Symptoms	Number of Days			
		1-3 N(%)	4-7 N(%)	8-14 N(%)	>14 N(%)
Bruising	5	3 (60.0%)	0 (0.0%)	2 (40.0%)	0 (0.0%)
Swelling	13	10 (76.9%)	1 (7.7%)	1 (7.7%)	1 (7.7%)
Redness	4	1 (25.0%)	2 (50.0%)	0 (0.0%)	1 (25.0%)
Pain	4	2 (50.0%)	0 (0.0%)	2 (50.0%)	0 (0.0%)
Itching	0	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other	62	27 (43.5%)	0 (0.0%)	1 (1.6%)	34 (54.8%)

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Should I tell my doctor what medications I am taking?

Yes. You should tell your doctor about all the medicines you are taking, even over the counter medicines or treatments. If you are taking blood thinners or medications that may interfere with clotting of the blood, such as aspirin, you might be more likely to have bruising or bleeding at the injection site. There have been no studies of possible interactions between Radiesse and drugs or other substances or implants. Talk to your doctor about your medical history when deciding on treatment options.

What can I expect after treatment?

Immediately following a treatment session with Radiesse; redness, bruising or swelling may occur in the treatment area. These side effects usually go away in a short period and are generally mild in nature. An ice pack may be applied to the treatment area to help reduce swelling. Your doctor will give you specific post-treatment care instructions.

For approximately 24 hours after treatment:

- Avoid significant movement or massage of the treated area.
- Do not apply makeup.
- Avoid extensive sun or heat exposure.

After you leave the office, you may experience redness, bruising or swelling for a few days. Not all patients experience these, but please remember that such side effects can occur and are not out of the ordinary for such a treatment.

You may be able to feel the area where Radiesse was injected for some period after injection. Over time, the injected area will feel more and more like your own tissue.

How quickly can I get back to my daily activities?

Most patients feel comfortable going back to their normal activities immediately after treatment with Radiesse.

What other things do I need to know?

The Microspheres in Radiesse can be seen in X-rays and CT Scans. It is very important that you inform your doctor and other health care professionals that you have Radiesse injected in your face. Even though Radiesse can be seen in X-rays and CT Scans, there is not a high risk that it would cause your doctor concern, as long as s/he knows that you have had Radiesse injected in your face.

An Immediate, Long Lasting Way to Correct Facial Wasting



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