

A PATIENT'S GUIDE

RADIESSE® For The Correction Of Moderate To Severe Facial Wrinkles And Folds, Such As Nasolabial Folds



- ◆ 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.

A PATIENT'S GUIDE TO RADIESSE

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.

Calcium Hydroxylapatite:

Calcium Hydroxylapatite is a biocompatible (compatible with living systems), biodegradable (dissolves in the body) material. Calcium hydroxylapatite is identical in composition to the mineral portion of teeth and bone.

Granuloma:

A small area of swelling (inflammation) in the body due to tissue injury, such as from an infection.

Nodule:

A lump or growth.

Side effect:

An undesirable event caused by use of the product.

BACKGROUND INFORMATION

What is Radiesse?

Radiesse is an injectable for facial folds and wrinkles. Calcium Hydroxylapatite has a history of safe use in otology (ears), laryngeal (vocal chords), and dental and orthopedic applications (see glossary).

What is Radiesse used for?

Radiesse is used to fill moderate to severe facial wrinkles and folds, such as nasolabial folds—the creases that extend from the corner of your nose to the corner of your mouth. Radiesse will not correct the underlying causes.

Can Radiesse work for me?

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 should also not choose Radiesse if you desire only short-term results.

How does Radiesse work?

Once injected, Radiesse immediately adds fullness to your face giving you a visible result at the first treatment session. Radiesse contains microspheres made of a natural material called Calcium Hydroxylapatite in a water based gel carrier.

How long do treatment effects last?

Although treatment effects will differ for each person, in a clinical study, Radiesse lasted up to six months.

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.

Are skin tests needed before treatment with Radiesse?

No skin testing is required prior to use.

Should I tell my healthcare provider 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.

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 side effects are redness, bruising, or swelling. These side effects 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 types of side effects reported in a clinical study of 117 patients with Radiesse and another similar product (Tables 1 – 4).

**Table 1. Side Effects Reported Through Patient Diaries
Number of Patients With at Least One Side Effect By Side Effect Type**

	RADIESSE Total N(%)	Control Total N(%)
Bruising	74 (63.2)	50 (42.7)
Swelling	81 (69.2)	62 (53.0)
Redness	78 (66.7)	84 (71.8)
Granuloma	0 (0.0)	0 (0.0)
Needle Jamming Nodule	0 (0.0) 1 (0.9)	0 (0.0) 1 (0.9)
Pain	33 (28.2)	26 (22.2)
Itching	21 (18.0)	24 (20.5)
Other	35 (29.9)	26 (22.2)

**Table 2. Side Effects Reported Through Patient Diaries
Number of Patients With at Least One Side Effect By Side Effect Type**

	RADIESSE Total N(%)	Control Total N(%)
Bruising	0 (0.0)	2 (1.7)
Swelling	5 (4.3)	4 (3.4)
Redness	6 (5.1)	9 (7.7)
Granuloma	0 (0.0)	0 (0.0)
Needle Jamming Nodule	1 (0.9) 0 (0.0)	0 (0.0) 2 (1.7)
Pain	2 (1.7)	1 (0.9)
Itching	1 (0.9)	2 (1.7)
Other	3 (2.6)	3 (2.6)

**Table 3. Length of Time for Side Effects
Reported Through Patient Diaries By Type of Side Effect**

	RADIESSE Total Reporting Symptoms N(%)	Control Total Reporting Symptoms N(%)	RADIESSE Number of Days				Control Number of Days			
			1-3 N(%)	4-7 N(%)	8-14 N(%)	>14 N(%)	1-3 N(%)	4-7 N(%)	8-14 N(%)	>14 N(%)
Bruising	91 (60.3)	60 (39.7)	16 (10.6)	37 (24.5)	33 (21.9)	5 (3.3)	15 (9.9)	29 (19.2)	12 (7.9)	4 (2.6)
Swelling	104 (54.5)	87 (45.5)	34 (17.8)	43 (22.5)	17 (8.9)	10 (5.2)	34 (17.8)	39 (20.4)	10 (5.2)	4 (2.1)
Redness	105 (45.1)	128 (54.9)	39 (16.7)	26 (11.2)	19 (8.2)	21 (9.0)	45 (19.3)	35 (15.0)	16 (6.9)	32 (13.7)
Granuloma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Needle Jamming Nodule	0 (0.0) 1 (50.0)	0 (0.0) 1 (50.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	1 (50.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)
Pain	40 (54.8)	33 (45.2)	22 (30.1)	13 (17.8)	4 (5.5)	1 (1.4)	20 (27.4)	10 (13.7)	2 (2.7)	1 (1.4)
Itching	24 (47.1)	27 (52.9)	15 (29.4)	5 (9.8)	3 (5.9)	1 (2.0)	11 (21.6)	10 (19.6)	3 (5.9)	3 (5.9)
Other	52 (56.5)	40 (43.5)	15 (16.3)	17 (18.5)	8 (8.7)	12 (13.0)	8 (8.7)	10 (10.9)	11 (12.0)	11 (12.0)

**Table 4. Length of Time for Side Effects
Reported Through Other Methods By Type of Side Effect**

	RADIESSE Total Reporting Symptoms N(%)	Control Total Reporting Symptoms N(%)	RADIESSE Number of Days				Control Number of Days			
			1-3 N(%)	4-7 N(%)	8-14 N(%)	>14 N(%)	1-3 N(%)	4-7 N(%)	8-14 N(%)	>14 N(%)
Bruising	0 (0.0)	2 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (50.0)	1 (50.0)	0 (0.0)
Swelling	5 (41.7)	7 (58.3)	5 (41.7)	0 (0.0)	0 (0.0)	0 (0.0)	5 (41.7)	0 (0.0)	0 (0.0)	2 (16.7)
Redness	9 (42.9)	12 (57.1)	4 (19.0)	2 (9.5)	2 (9.5)	1 (4.8)	2 (9.5)	14 (34.3)	3 (19.0)	3 (14.3)
Granuloma	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Needle Jamming Nodule	1 (100.0) 0 (0.0)	0 (0.0) 3 (100.0)	1 (100.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0) 0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (33.3) 2 (66.7)
Pain	3 (75.0)	1 (25.0)	1 (25.0)	1 (25.0)	0 (0.0)	1 (25.0)	1 (25.0)	0 (0.0)	0 (0.0)	0 (0.0)
Itching	1 (33.3)	2 (66.7)	0 (0.0)	0 (0.0)	1 (33.3)	0 (0.0)	1 (33.3)	0 (0.0)	1 (33.3)	0 (0.0)
Other	4 (50.0)	4 (50.0)	1 (12.5)	0 (0.0)	2 (25.0)	1 (12.5)	1 (12.5)	1 (12.5)	0 (0.0)	2 (25.0)

The Next Generation in Longer Lasting Wrinkle Correction



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