

A PATIENT'S GUIDE

RADIESSE® Dermal Filler 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® DERMAL FILLER

INTRODUCTION

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

Please read this information and discuss any questions with your doctor. Only you and your doctor can decide whether RADIESSE filler 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 dermal filler?

Radiesse dermal filler 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 dermal filler used for?

Radiesse dermal filler 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 filler will not correct the underlying causes.

Can Radiesse dermal filler work for me?

Talk to your doctor about your medical history when deciding on treatment options. You should not use Radiesse dermal filler if you are allergic to any of its ingredients. You should also not choose Radiesse filler if you desire only short-term results.

How does Radiesse dermal filler work?

Once injected, Radiesse dermal filler immediately adds fullness to your face giving you a visible result at the first treatment session. Radiesse filler 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 dermal filler lasted up to six months.

Do injections of Radiesse dermal filler hurt?

As with any injection, injections with Radiesse dermal filler may hurt. Radiesse filler 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 dermal filler?

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 dermal filler and drugs or other substances or implants.

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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 dermal filler 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 dermal filler?

Talk to your doctor about the possible side effects of RADIESSE dermal filler. 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 filler. 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 filler 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	Control
	Total N(%)	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	0 (0.0)	0 (0.0)
Nodule	1 (0.9)	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. Physician Reported Side Effects
Number of Patients With at Least One Side Effect By Side Effect Type

	RADIESSE	Control
	Total N(%)	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	1 (0.9)	0 (0.0)
Nodule	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				Control			
			Number of Days				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	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)
Nodule	1 (50.0)	1 (50.0)	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				Control			
			Number of Days				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)	3 (14.3)	4 (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	1 (100.0)	0 (0.0)	1 (100.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nodule	0 (0.0)	3 (100.0)	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)	0 (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)

What can I expect after treatment?

Immediately following a treatment session with RADIESSE dermal filler redness, bruising or swelling may occur in the treatment area. These signs 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 health care provider 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 note that such effects can occur and are not out of the ordinary for such a treatment.

You may be able to feel the area where RADIESSE dermal filler 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 dermal filler.

How many treatments are required?

Your doctor will decide with you the number of treatment sessions and the amount of RADIESSE dermal filler you will need at each treatment session. Generally, significant changes may be achieved in a first treatment. A touch-up may be required to achieve optimal results.

Without touch-up injections, how will my skin look?

Your skin will begin to gradually look like it did before treatment as you near the end of the time period RADIESSE dermal filler usually lasts. Periodic touch up injections will help you maintain the look you have after treatment.

What other things do I need to know?

The Microspheres in RADIESSE filler 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 filler injected in your face. Even though RADIESSE filler 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 filler injected in your face.

The Next Generation in Longer Lasting Wrinkle Correction



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