

## **RADIESSE<sup>®</sup> & RADIESSE<sup>®</sup> (+)**

**NLF**

**Consumer ISI**

### **What are RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+)?**

RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+) are dermal fillers that are used for smoothing 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<sup>®</sup> and RADIESSE<sup>®</sup> (+) IMPORTANT SAFETY INFORMATION**

#### **Who should not use RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+)?**

You should not use RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+) if you have an allergy to any component of the product, if you have a history of severe allergies, if you have a bleeding disorder, or if you are pregnant or breastfeeding. You should not use RADIESSE<sup>®</sup> (+) if you have an allergy to lidocaine or medicines like it.

#### **What is the most important information I should know about RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+)?**

One of the risks with using these products 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.

As with all procedures that involve an injection through the skin, there is a risk of infection.

Do not use RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+) if you have a skin infection until it has healed.

It is not known if RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+) is safe or effective in the lips, or in the area around the eyes.

The microspheres in RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+) can be seen in X-rays and CT Scans. It is very important that you tell your health care provider that you have had RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+) dermal filler injected into your face.

If you have a history of herpes, you may experience a herpes breakout after receiving RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+).

You should minimize strenuous activity and avoid extensive sun or heat exposure for about 24 hours after treatment and until any swelling or redness has resolved.

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**What should I tell my doctor before using RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+)?**

Tell your health care provider if you are taking blood thinners or medicines that can interfere with the clotting of blood, such as aspirin or warfarin. These medicines might make it more likely that you will experience bruising or bleeding at the injection site. Tell your health care provider if you have a history of forming large, raised scars or if you have had any other skin treatments such as skin peels.

**What are the most common adverse events with RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+)?**

The most common adverse events seen in clinical studies of RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+) include bruising, redness, swelling, pain, itching and other local side effects.

These are not all of the possible side effects with RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+). Merz collects information about adverse events seen with RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+) post-approval. These events are included in the RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+) Patient Information Guide based on an assessment of seriousness and potential causal relationship to RADIESSE<sup>®</sup> or RADIESSE<sup>®</sup> (+). Please see the Patient Information Guide available at [www.Radiesse.com](http://www.Radiesse.com) for a list of these events. Tell your health care provider about any side effects that bother you or do not go away.

Important: For full safety information, please visit [www.Radiesse.com](http://www.Radiesse.com) or call MyMerz Solutions at 1-844-469-6379

RADIESSE<sup>®</sup> and RADIESSE<sup>®</sup> (+) are available by prescription only.