



## MERZ PHARMA CANADA ANNOUNCES THE APPROVAL OF RADIESSE® (+) WITH INTEGRAL 0.3% LIDOCAINE

*Radiesse® (+) provides immediate lift with enhanced injection comfort<sup>1</sup>*

TORONTO, ONTARIO – JULY 15, 2015 – BUSINESS WIRE – Merz Pharma Canada, Ltd., affiliate of the global Merz Pharma Group, today announced that [Radiesse® \(+\)](#) with integral 0.3% Lidocaine (“Radiesse® Plus”) has received Health Canada approval and will be available to Canadian physicians in July 2015. Treatment with Radiesse® (+) immediately replenishes lost volume as well as providing significant reduction in pain due to the addition of lidocaine.<sup>1</sup>

“With the introduction of Radiesse® (+), we are proud to be able to provide physicians in Canada with a safe, effective volumizing filler that enhances patient comfort and eliminates the need for in-office lidocaine mixing,” said Bob Bennett, President and General Manager for Merz Pharma Canada. “As we continue to expand our presence in the aesthetics space, we look forward to bringing new products and additional indications to the market in order to expand the options available to our physician customers.”

Radiesse® (+) injectable implant is an opaque, dermal filler that contains a small quantity of local anesthetic (lidocaine). Radiesse® (+) is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for the rejuvenation of the hands. The presence of lidocaine is intended to reduce the patient’s pain during treatment.

“Merz continues to make meaningful investments in research and development programs in order to continue to bring new products to physicians and patients in North America,” said David Dobrowski, Vice President and Head of North American Research and Development. “The Health Canada approval of [Radiesse® \(+\)](#) with integral 0.3% Lidocaine is the result of those efforts and provides an important complementary addition to our current aesthetics portfolio.”

In a clinical study, 101 patients received Radiesse® on one side of the face and Radiesse® (+) on the other side of the face. Patients rated their pain on a scale of 0 to 10. On the scale, 0 was no pain and 10 was very severe pain. Immediately after injection, patients rated their pain about 6.7 on a scale of 0 to 10 for the side of the face injected with Radiesse® compared to about 2.3 on the same scale for the side of the face treated with Radiesse® (+). Sixty (60) minutes after treatment, patients rated their pain about 1.1 on a scale of 0 to 10 for the side of the face injected with Radiesse® compared to about 0.3 on the same scale for the side of the face treated with Radiesse® (+).

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<sup>1</sup> IFU Radiesse® with Lidocaine

### **About RADIESSE® (+)**

Radiesse® (+) is an opaque dermal filler that contains a small quantity of local anesthetic (lidocaine). Radiesse® (+) is indicated for subdermal implantation for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for the rejuvenation of the hands. Radiesse® (+) is composed of calcium hydroxylapatite (CaHA) microspheres suspended in a water-based gel carrier. Radiesse® was first approved by Health Canada in November 2005 for the correction of moderate to severe facial wrinkles and folds, such as nasolabial folds and for the rejuvenation of the hand.

### **About Merz North America**

Merz North America is a specialty healthcare company that develops and commercializes innovative, high-quality treatment solutions in aesthetics, dermatology and neurosciences in the U.S. and Canada. As part of the Merz Pharma Group of companies, our ambition is to become the most admired, trusted and innovative aesthetics and neurotoxin company. By developing products that improve patients' health and help them to live better, feel better and look better, we will continue to make significant contributions to the well-being of individuals around the world. With the acquisitions of **NEOCUTIS** and Ulthera, Merz is building an aesthetics portfolio with a range of treatment options (device, injectables and topicals) that allow physicians to use Merz technologies to treat a broader range of patients and concerns.

For more information about Merz Pharma Canada, Ltd. or their product portfolio, please visit [www.merzcanada.com](http://www.merzcanada.com). For information regarding Merz products and operations in the United States, please visit [www.merzusa.com](http://www.merzusa.com).

RADIESSE is a registered trademark of Merz North America, Inc.

### **RADIESSE® (+) IMPORTANT SAFETY INFORMATION**

**Contraindications:** RADIESSE (+) injectable implant is contraindicated for patients with severe allergies manifested by a history of anaphylaxis, or history or presence of multiple severe allergies; with hypersensitivity to any of the components; with bleeding disorders, that are prone to inflammatory skin conditions; with a tendency for developing hypertrophic scars; and with patients with systemic disorders which cause poor wound healing or will lead to tissue deterioration over the implant. It is contraindicated in the presence of foreign bodies such as liquid silicone or other particulate materials. It should not be used for correction of the glabellar folds; a higher incidence of necrosis has been associated with glabellar injection. It should not be used in areas where there is inadequate coverage of healthy, well vascularized tissue. It is not intended for use in the breasts and in the lips.

**Warnings:** Use of RADIESSE (+) in any person with active skin inflammation or infection in or near the treatment should be deferred until the inflammatory or infectious process is controlled. Injection procedure reactions have been observed, mainly short-term (less than 7 days) bruising, redness, Special care should be taken to avoid injection into the blood vessels. Introduction into the vasculature may occlude the vessels and could cause infarction or embolism leading to ischemia, necrosis or scarring; this has been reported to occur in the lips, nose, glabellar or ocular area. Although rare, loss of vision is also possible; this has been reported to occur in the nasolabial folds, oral commissures, lips, nose, glabellar or ocular area. Do not overcorrect (overfill) a contour deficiency with RADIESSE (+) because the depression should gradually improve within several weeks as the treatment effect of RADIESSE (+) occurs. The safety and effectiveness for use in the lips has not been established.

**Precautions:** RADIESSE (+) contains calcium hydroxylapatite, radiopaque particles, that are visible on CT Scans and may be visible in standard radiography. Nodules may form, requiring treatment or removal. Irregularity of the implant may occur which may require a surgical procedure to correct. As with all skin-injection procedures, there is a risk of infection with RADIESSE (+). Patients using medications that can prolong bleeding, such as aspirin or warfarin, may experience increased bruising or bleeding at the injection site. Patients should minimize exposure of the treated area to extensive sun or heat exposure for approximately 24 hours after treatment or until any initial swelling and redness has resolved. Safety of RADIESSE (+) beyond 3 years; in the periorbital area; with concomitant dermal therapies or other drugs or implants; in patients with susceptibility to keloid formation and hypertrophic scarring; in pregnancy, in breastfeeding females or in patients under 18 years has not been established. Patients with a history of herpetic eruption may experience reactivation of herpes.

**Adverse Events:** The most commonly reported serious adverse events in post-market surveillance of with RADIESSE include serious edema, infection, allergic reaction, and necrosis.

To report a problem with RADIESSE, please call Merz Pharma Canada Customer Service at 1-866-815-8715.

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