

Calcium hydroxylapatite

Brand Name: Radiesse

Drug Class: Opportunistic Infection and Other Drugs

Drug Description

Radiesse is a soft-tissue augmentation product composed of smooth calcium hydroxylapatite (CaHA) particles suspended in a water-based gel carrier. [1] [2]

HIV/AIDS-Related Uses

Radiesse was approved by the FDA on December 22, 2006, as a cosmetic dermal filler for use in the long-term correction of facial lipoatrophy associated with antiretroviral treatment in HIV infected people.[3] [4]

Non-HIV/AIDS-Related Uses

Radiesse was approved by the FDA on December 22, 2006, for use as filler material to correct facial lines and wrinkles, such as nasolabial folds.[5] Radiesse is approved for use worldwide in facial plastic and reconstructive surgery.[6]

Other FDA-approved soft-tissue augmentation indications of synthetic CaHA include tissue marking, treatment of vocal cord insufficiency, and treatment of oral-maxillofacial defects. Similar products containing CaHA are approved for the treatment of stress urinary incontinence and are used in products for dental ridge augmentation, bone augmentation, and otology implants.[7]

Pharmacology

CaHA is the principal inorganic constituent in human bones and teeth.[8] CaHA in Radiesse is a biocompatible, biodegradable material that is synthetically manufactured to be chemically and biologically identical to the natural substance.[9]

Radiesse contains sterile and nonpyrogenic CaHA microspheres in an aqueous carrier of glycerin, sterile water for injection, and sodium carboxymethylcellulose.[10] [11] After the carrier dissipates in vivo, CaHA particles remain below the skin in the injected area. The active ingredient of Radiesse, CaHA, has been studied extensively in the United States and worldwide; it has been proven safe and effective for various dermal filler

uses.[12]

Radiesse is injected subcutaneously to increase skin thickness. Its CaHA microspheres appear in x-rays and CT scans.[13] After Radiesse is injected, the gel carrier dissipates in vivo, and CaHA particles remain at the injection site to provide durable bulking treatment.[14] The CaHA particles act by directly filling space in the soft tissue and by providing a microstructure for tissue infiltration. In addition, Radiesse may promote new collagen binding.[15]

A prospective, open-label study of Radiesse for the treatment of lipoatrophy was conducted in 100 HIV infected patients. The primary endpoint of efficacy and secondary endpoint of safety were evaluated at Months 1, 3, 6, and 12. All patients met the primary endpoint of improved aesthetics at Months 3 and 6, and all patients continued to improve by Month 12.[16] [17]

Adverse Events/Toxicity

Radiesse and other products containing CaHA appear safe and well tolerated. The most common adverse effects with Radiesse treatment are redness, bruising, and swelling at the injection site; all of these side effects appear transient and mild.[18] [19]

Mild to moderate echymosis, edema, erythema, pain, and pruritis have occurred in HIV infected patients receiving Radiesse in clinical trials. Severe experiences were of short duration, were expected, and did not affect treatment outcome. The most common other adverse effect was mildly uneven skin contours and irregularities, which resolved with additional injections. No systemic or serious adverse effects were reported that were associated with treatment.[20]

In a study of Radiesse for the treatment of HIV-associated lipoatrophy, no clinically significant events occurred. Although 51% of patients in this study were considered people of color, depth of color did not appear to predict the occurrence of adverse effects. Thus, Radiesse is considered safe for use in people of color.[21]

Calcium hydroxylapatite



Adverse Events/Toxicity (cont.)

When Radiesse was studied for the correction of nasolabial folds in 117 patients, 82% of nasolabial folds treated with Radiesse improved after 6 months. This was a significantly greater percentage than with the control, which showed improvement in only 27% of treated folds (p less than 0.0001). No granulomas occurred; the rate of nodule formation was low and was the same in control and treatment arms.[22]

Contraindications

Radiesse is contraindicated for short-term augmentation or restoration. Radiesse should not be used in patients who are allergic to any of its components (sodium carboxymethylcellulose, sterile water for injection, and glycerin).[23] [24]

Clinical Trials

For information on clinical trials that involve Calcium hydroxylapatite, visit the ClinicalTrials.gov web site at <http://www.clinicaltrials.gov>. In the Search box, enter: Calcium hydroxylapatite AND HIV Infections.

Dosing Information

Mode of Delivery: Subcutaneous injection.[25]

Dosage Form: Single-use syringe containing 0.3, 1, or 1.3 ml of solution with active CaHA particles suspended in each needle in a gel carrier.[26]
Radiesse is injected subcutaneously through a very fine needle.[27]

Chemistry

Molecular weight: CaHA particles sized 25 to 45 microns[28]

Physical Description: Flexible, semisolid, cohesive implant.[29]

Other Names

Radiance FN[30]

CaHA[31]

Further Reading

Comite SL, Liu JF, Balasubramanian S, Christian MA. Treatment of HIV-associated facial lipoatrophy with Radiance FN (Radiesse). *Dermatol Online J.* 2004 Oct 15;10(2):2.

Silvers SL, Eviatar JA, Echavez MI, Pappas AL. Prospective, open-label, 18-month trial of calcium hydroxylapatite (Radiesse) for facial soft-tissue augmentation in patients with human immunodeficiency virus-associated lipoatrophy: one-year durability. *Plast Reconstr Surg.* 2006 Sep;118(3 Suppl):34S-45S.

Manufacturer Information

Calcium hydroxylapatite
BioForm Medical, Inc.
1875 South Grant St. Suite, #110
San Mateo, CA 94103
(650) 286-4000

Radiesse
BioForm Medical, Inc.
1875 South Grant St. Suite, #110
San Mateo, CA 94103
(650) 286-4000

For More Information

Contact your doctor or an AIDSinfo Health Information Specialist:

- Via Phone: 1-800-448-0440 Monday - Friday, 12:00 p.m. (Noon) - 5:00 p.m. ET
- Via Live Help: http://aidsinfo.nih.gov/live_help Monday - Friday, 12:00 p.m. (Noon) - 4:00 p.m. ET

Calcium hydroxylapatite



References

1. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
2. BioForm Medical, Inc. - Press Releases: FDA Approves Radiesse Facial Filler for Two New Aesthetic Indications [press release], December 27, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_122706.pdf. Accessed 12/29/06.
3. BioForm Medical, Inc. - Press Releases: FDA Advisory Panel Recommends Approval of Radiesse for Two Facial Aesthetic Applications [press release], August 24, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_082406.pdf. Accessed 12/29/06.
4. FDA - List Serve Archive: FDA approves Radiesse for treating facial lipoatrophy [press release], December 22, 2006. Available at: <http://www.fda.gov/oashi/aids/listserve/listserve2006.html#122906>. Accessed 12/29/06.
5. BioForm Medical, Inc. - Press Releases: FDA Advisory Panel Recommends Approval of Radiesse for Two Facial Aesthetic Applications [press release], August 24, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_082406.pdf. Accessed 12/29/06.
6. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
7. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
8. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
9. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
10. BioForm Medical, Inc. - Press Releases: FDA Approves Radiesse Facial Filler for Two New Aesthetic Indications [press release], December 27, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_122706.pdf. Accessed 12/29/06.
11. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
12. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
13. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
14. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
15. BioForm Medical, Inc. - Press Releases: FDA Approves Radiesse Facial Filler for Two New Aesthetic Indications [press release], December 27, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_122706.pdf. Accessed 12/29/06.
16. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
17. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
18. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
19. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
20. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
21. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
22. BioForm Medical, Inc. - Press Releases: FDA Approves Radiesse Facial Filler for Two New Aesthetic Indications [press release], December 27, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_122706.pdf. Accessed 12/29/06.
23. FDA - Dockets Management: Radiesse for HIV Lipoatrophy: Proposed Patient Labeling. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_05.pdf. Accessed 12/29/06.
24. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
25. BioForm Medical, Inc. - Press Releases: FDA Advisory Panel Recommends Approval of Radiesse for Two Facial Aesthetic Applications [press release], August 24, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_082406.pdf. Accessed 12/29/06.
26. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.
27. BioForm Medical, Inc. - Press Releases: FDA Advisory Panel Recommends Approval of Radiesse for Two Facial Aesthetic Applications [press release], August 24, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_082406.pdf. Accessed 12/29/06.

Calcium hydroxylapatite



28. BioForm Medical, Inc. - Press Releases, August 24, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_082406.pdf. Accessed 12/29/06.

29. FDA - Dockets Management: Radiesse for Soft Tissue Augmentation for the Treatment of HIV-Associated Facial Lipoatrophy. Available at: http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4233b1_02.pdf. Accessed 12/29/06.

30. Dermatol Online J - 2004 Oct 15;10(2):2

31. BioForm Medical, Inc. - Press Releases, August 24, 2006. Available at: http://www.radiesse.com/pdf/pr/pr_082406.pdf. Accessed 12/29/06.