

# Bellafill® Cosmetic Skin Treatment FAQs

## Bellafill®

Q: What is Bellafill®?

A: Bellafill® is a smooth collagen-based dermal filler with polymethylmethacrylate (PMMA) microspheres. The collagen gel in Bellafill® provides immediate volume and lift to correct the wrinkle/nasolabial fold and/or acne scar. The PMMA microspheres remain in place and create a base that provides structural support for smoother-looking skin.<sup>1\*</sup>

Q: Will it work for me?

A: In a clinical trial, Bellafill® was shown to work equally well with all skin types, and in men and women. If you have had a positive reaction to the Bellafill Skin Test, have a history of severe allergies, have known bovine collagen allergies, are allergic to lidocaine, have bleeding disorders or are prone to thick scar formation and/or excessive scarring, you should not receive Bellafill.

Q: Is it safe?

A: Bellafill® has been proven safe through 5 years in the largest and longest prospective dermal filler study ever conducted.<sup>2\*\*</sup>

Q: What's the downtime?

A: You can return to normal activities right away. You may experience temporary swelling, redness, pain, bruising, lumps/bumps, itching, and discoloration at the treatment site. These side effects are usually transient and typically resolve within 1–7 days.<sup>2</sup>

Q: Who can receive treatment with Bellafill®?

A: Patients must be 21 years of age or older, and receive the required negative skin test prior to treatment. In clinical studies, Bellafill® was shown to work in all skin types, and in men and women. If you have had a positive reaction to the Bellafill Skin Test, have a history of severe allergies, have known bovine collagen allergies, are allergic to lidocaine, have bleeding disorders, or are prone to thick scar formation and/or excessive scarring, you should not receive Bellafill. Please consult with your physician and refer to the Instructions for Use for a full list of contraindications.

1. Data on file. Suneva Medical, Inc.
2. Bellafill® [Instructions for Use]. San Diego, CA: Suneva Medical, Inc.; 2015.
3. American Academy of Dermatology, [http://www.aad.org/media-resources/stats-and-facts/conditions/acne#Uc2hG\\_nvt8F](http://www.aad.org/media-resources/stats-and-facts/conditions/acne#Uc2hG_nvt8F).
4. Journal of Plastic, Reconstructive and Aesthetic Surgery, 2008, <http://www.sciencedirect.com/science/article/pii/S1748681508003951>.
5. Formula PR Independent Study, 2013.

\*Proposed mechanism of action

\*\*Based on 5 year post approval study on the correction of nasolabial folds.

\*\*\*The indication for correction of nasolabial folds (smile lines) was approved based on a pivotal clinical study, where effectiveness was observed out to 12 months (primary effectiveness endpoint was at 6 months).

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Q: How much does Bellafill® cost?

A: The cost of Bellafill® varies depending on how many syringes are required to obtain optimal correction. Your licensed provider can personalize a treatment plan that fits your time and budget during your consultation.

Q: How long does it last?

A: Satisfaction and effectiveness for the correction of nasolabial folds have been established through 5 years. Effectiveness for the correction of acne scars has been proven through 12 months.<sup>2\*\*\*</sup>

### **Important Safety Information**

Bellafill® is indicated for the correction of nasolabial folds and moderate to severe, atrophic, distensible facial acne scars on the cheek in patients over the age of 21 years. Patients who have had a positive reaction to the Bellafill® Skin Test, have a history of severe allergies, have known bovine collagen allergies, are allergic to lidocaine, have bleeding disorders or are prone to thick scar formation and/or excessive scarring should not receive Bellafill®. The safety of Bellafill® for use during pregnancy, breastfeeding, or in patients under 21 has not been established. You may experience temporary swelling, redness, pain, bruising, lumps/bumps, itching, and discoloration at the treatment site. These side effects are usually transient and typically resolve within 1–7 days. You may experience lumps/bumps/papules that may occur more than one month after injection and that may persist. Less common side effects include rash and itching more than 48 hours after treatment, persistent swelling or redness, lumps/bumps, acne, and increased sensitivity at treatment sites. Infrequently, granulomas may occur and may be treated by your licensed physician provider. Be sure to call your licensed provider immediately if you notice any unusual skin reactions around the treatment area. Based on the 5-year Post-Approval Study on nasolabial folds with 1,008 patients, long-term safety of Bellafill® for up to 5 years has been established. For more safety information, please consult with your physician and the patient labeling that can be found by visiting [www.bellafill.com](http://www.bellafill.com).

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3. American Academy of Dermatology, [http://www.aad.org/media-resources/stats-and-facts/conditions/acne#Uc2hG\\_nvt8F](http://www.aad.org/media-resources/stats-and-facts/conditions/acne#Uc2hG_nvt8F).
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