Assessing and *treating* patients with HArmonyCa®

Adverse events should be reported to Allergan Aesthetics, an AbbVie company, by emailing AGN-DL-AUSDermalinternationalComplaints@abbvie.com, or by calling 1-800-624-4261.

HArmonyCa® Lidocaine is a dermal filler intended for facial soft tissue augmentation and should be injected into the deep dermal, sub-dermal, or supra-periosteal layers in the midface (cheek and malar areas), lateral face, and jawline. The lidocaine in the product is for reducing pain during treatment.

The safety and efficacy of HArmonyCa® has not been evaluated in patients treated with other filling implants. There is no data available regarding the safety of injecting a greater amount than 20 mL of ALLERGAN dermal fillers per 60 kg body mass per year.

HArmonyCa® Lidocaine is referred to as HArmonyCa®.
CA-HAR-260006 April 2026

HArmonyCa®

Allergan Aesthetics
an AbbVie company

Contents

Introducing HArmonyCa®

HArmonyCa® is powered by DART™ — Dual Action Rejuvenating Technology[1,2]

HArmonyCa® combines CaHA with HA in **one dual-action injectable, delivered as a single treatment**[3]

Discover the dual action of HArmonyCa®:

- **An instant lift that holds**

HA particles diffuse between collagen fibres of the lower dermal layer for an immediate lifting effect.*[,4]

- **Sustained collagen stimulation**

CaHA microspheres work deep within the dermis to form a scaffold that supports fibroblast function.[5] As the HA-based carrier gel degrades over time, CaHA supports the body's own collagen production to build a firm and dense framework in its place, for a long-lasting lift.†[,6,7]

CaHA: calcium hydroxyapatite; HA: hyaluronic acid; EI: evaluating investigator; MFVDS: Midface Volume Deficit Scale; GAIS: Global Aesthetic Improvement Scale; mITT: modified intention-to-treat

*Results derived from an animal model study comparing fillers.[4]

†The clinical effects of CaHA can last 1–3 years.[7]

‡Results from a pre-clinical animal study of HArmonyCa®, with results demonstrated over 12 weeks, showed that HArmonyCa® led to an instant and sustained lift following injection.[8]

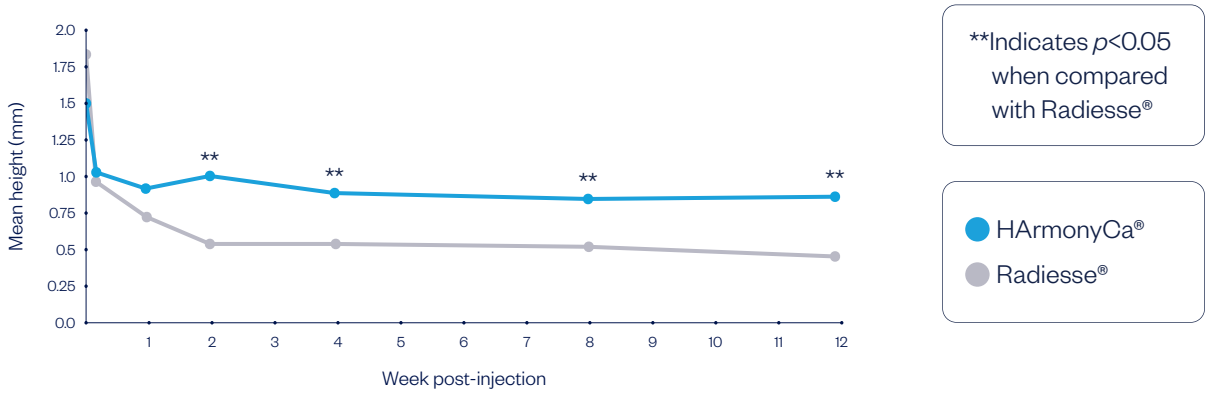
§Results from a 1-year, prospective, open-label, post-marketing study where HArmonyCa® and HArmonyCa® Lidocaine were injected in the midface of 140 patients with moderate to severe midface volume deficit. The primary endpoint was responder status based on EI-assessed MFVDS at Month 1. Secondary endpoints included responder status based on EI-assessed and participant-assessed GAIS change from baseline on FACE-Q Satisfaction with Cheeks questionnaire, and change from baseline on FACE-Q Satisfaction with Facial Appearance questionnaire. The mITT population was all treated participants with non-missing baseline MFVDS score. At Month 1, the MFVDS responder status (a participant with at least a 1-grade improvement on the MFVDS based on the EI's live assessment of midface volume deficit) was 82.8% (95% CI: 75.7%–88.5%) in the mITT population for both treatment groups combined.[2]

¶Vectra® markerless tracking was used for dynamic assessment of skin surface changes along x, y, and z axes using vector arrows at Month 1, Month 3, Month 6, and Month 12 in the mITT population. Substantial displacement was seen in the overall midface at all timepoints, with the largest medial and vertical displacements observed at Months 3 and 6. This was an exploratory endpoint.[2]

Simplified treatment with a convenient, ready-to-use dual-action injectable[3]

HArmonyCa® offers a significantly greater lifting effect vs. Radiesse® with results observed as early as 2 weeks.[§,2]

Lift capacity with HArmonyCa® vs. Radiesse®: mean height over 12 weeks post-injection.[§,2]



Unlike CMC carrier gels in collagen stimulators like Radiesse®, HArmonyCa® is formulated with a durable HA-based carrier gel, creating an instant lift that holds.[‡,8,9]

In a separate clinical study (N=140), HArmonyCa® delivered a progressive lifting effect throughout the 1-year follow-up period. [§,¶,2]

CMC: carboxymethyl cellulose

Could *your patients benefit* from HArmonyCa® treatment?

A well-tolerated treatment with minimal downtime*,[10,11]

Side effects with HArmonyCa® are mostly mild and self-limiting.*,†,[2,10,11]

The most common AEs with HArmonyCa® are erythema, edema, pain, tenderness, and itching. These are typically mild and usually resolve within 48 hours.[10]

In an in vitro study, HArmonyCa® became degraded with hyaluronidase compared to the enzymatic degradation of Radiesse®.‡,§,[12]

AEs: adverse events; TEAE: treatment emergent adverse event

*Results from a retrospective, non-interventional study assessing the incidence and severity of TEAEs in adults (N=403) treated with HArmonyCa® Lidocaine at six clinics in Brazil.[10]
†In a post-marketing clinical analysis of HArmonyCa® (N=162), one unrelated serious AE was reported and one AE required medical intervention due to material migration into the lips and overcorrection.[10]
‡Results derived from an in vitro setting where the HA component of HArmonyCa® became degraded with hyaluronidase compared to the enzymatic degradation of Radiesse®.[12]
§Hyaluronidase is not licensed for treating complications associated with filler treatment. Responsibility for the use of hyaluronidase to manage complications arising from treatment with fillers remains at the discretion of the treating physician, and should be based on a complete assessment of the patient. Allergan Aesthetics, an AbbVie company, is not the marketing authorization holder for hyaluronidase, and cannot provide recommendations on the dosing and administration of hyaluronidase for the management of complications associated with filler treatment.

“My jawline is tighter, it feels smoother... my skin quality has improved.” *Mark, 49*

Our model, Mark, received a total of 3.9 mL of HArmonyCa® in the cheeks, jaw, and pre-auricular area. Mark also received pre-treatment with a total of 2.5 mL of JUVÉDERM® products in the cheeks and nasolabial folds, during a separate treatment visit, one day prior to their “before” photo.

Patient selection

The signs of aging skin

Over time, age affects the face in numerous ways, creating new treatment needs for your patients who want to maintain or combat the aging process.

With skin aging, a gradual loss of HA, collagen, and elastin can cause:[13]

Thinning of the dermis

Loss of elasticity

Go beyond single-agent collagen stimulators to tackle the complex needs of aging skin.[13]

The effects of aging in the *midface* and *lower face*

Aging causes structural changes

Structural changes include:

- Changes in dentition[15]
- Epidermis flattening[16]
- Atrophy of bone, muscles, and subcutaneous tissue[15,17]
- Loss of collagen and elastin[16]
- Movement and descent of fat compartments[17]

Structural changes lead to:

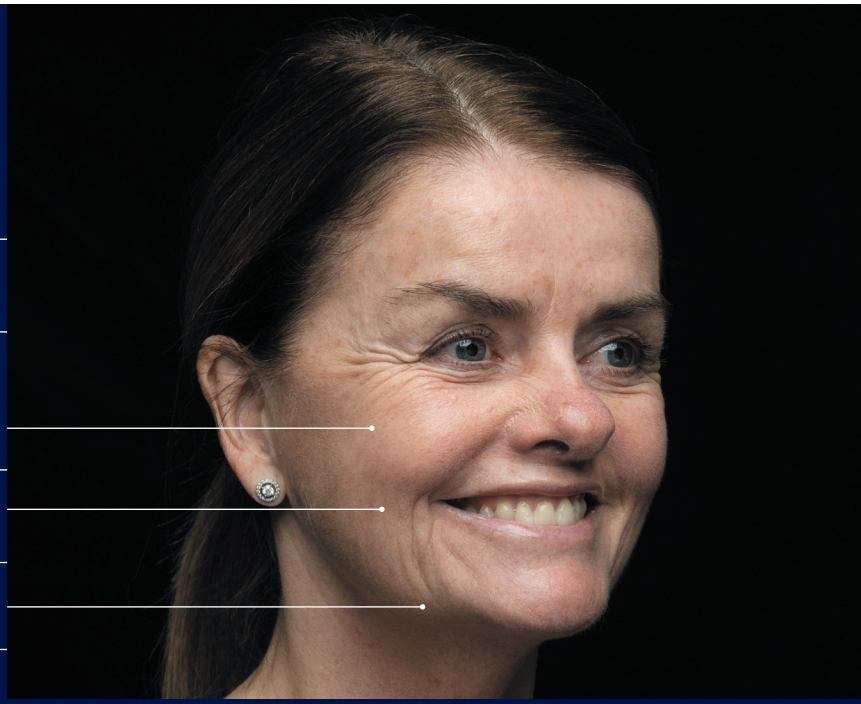
- Loss of definition in the jawline[17]
- Formation of jowls[17]
- Hyperdynamic expressions[14]
- Formation of nasolabial folds[18]
- Appearance of alterations in skin texture and pigmentation[18]
- Increased skin laxity and decreased skin tautness and elasticity[18]

How to select a suitable HArmonyCa® patient

Patients with facial skin laxity are potential HArmonyCa® patients.*,†,‡,[13]

Signs to help identify your next HArmonyCa® patient:§,[19]

- Lack of skin firmness
- Mild/moderate lateral cheek sagginess
- Accordion lines
- Mild/moderate jowling



FTV: facial tension vectors

*Results from a prospective and non-randomized interventional study where HArmonyCa® was injected in the pre-auricular region of 15 women. The primary endpoint was the volumetric changes at Day 180. Secondary endpoints included changes in facial tension vectors, time to filler tissue integration, and safety profile.[13]

†Ultrasound and elastography examinations were performed using the Samsung HT 30 ultrasound machine and the ElastoScan HS30/XH30, respectively (Samsung Healthcare Global). When compared to baseline, an increase in density, viscoelasticity, and firmness of the tissue was observed at 60 days and then confirmed at 90 days after treatment. At 180 days after treatment, an increase in collagen in the treated areas was confirmed.[13]

‡Vectra® H2 (Canfield Scientific, Inc.) was used to assess skin lift and tightening by measuring the changes in FTV at 60, 90, and 180 days after treatment. As compared to pre-treatment values, FTV significantly increased at all timepoints with a median (interquartile range) increase of 2.2 (1.6–2.2) mm and 2.0 (1.7–2.2) mm in the right and left side, respectively (p<0.0001 each), 180 days after treatment.[13]

§The responses of N=75 physicians when asked, "What signs of aging indicate the greatest suitability for HArmonyCa® treatment?"[19]

Assessment tools

Tools to help assess your patient's suitability for HArmonyCa® treatment:

Pinch test

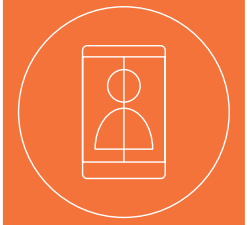
Assess your patient's skin tautness by pinching their skin[20]

- Pinch along the mandibular layer anterior to the antigonial angle
- Observe skin's ability to return to its original position

Soft tissue descent

Observe whether laxity is present in your patient's skin, after instructing them to tilt their head down[21]

Before images



Take images before treatment to help aid your assessment

3D images

3D imaging can help support you when assessing your patient's skin[22]

Cutometer®

Evaluate the viscoelastic properties of your patient's skin and its change with aging[23]

“I’m really pleased because I think it’s the best outcome.” *Lily, 39*

Lily received a total of 3.25 mL of HArmonyCa® in the cheeks, pre-auricular area, and jaw. The model also received pre-treatment with a total of 4 mL of JUVÉDERM® products in the chin and jaw during a separate treatment visit, one day prior to their “before” photo.

Injection technique

Injecting HArmonyCa® in the *midface* and *lower face*

Using a **retrograde fanning technique** in combination with a **22G cannula** 50 mm in length will help distribute HArmonyCa® evenly into your patient's skin. HArmonyCa® should be injected in the **subcutaneous plane.***[,19]

Injection technique

The C approach[19]

Treat patients using the C approach, which includes the zygomatic arch, jaw ramus, and jawline. Utilize the three entry points located in the jowl, jaw angle, and jaw ramus to achieve full coverage of the treatment areas.

*The responses of N=82 physicians when asked what injection technique and how many entry points they would suggest experienced injectors use to treat patients with HArmonyCa® and a survey of N=80 physicians when asked, "What injection technique do you use when administering HArmonyCa® to a typical patient in your clinic?" and of N=76 physicians when asked, "When you inject HArmonyCa® posterior to the ligament line, how many injection entry points do you usually use in your clinical experience?"[19]

It is possible to use a TSK STERIGLIDE 22G cannula 50 mm in length in combination with a retrograde fanning technique to help distribute HArmonyCa® evenly into your patient's skin.

The C approach

Three entry points

- Jowl
- Jaw angle
- Jaw ramus

Injecting HArmonyCa® in the *midface* and *lower face*

Using a **retrograde fanning technique** in combination with a **22G cannula** 50 mm in length will help distribute HArmonyCa® evenly into your patient's skin. HArmonyCa® should be injected in the **subcutaneous plane.***[,19]

The C+ approach*[,19]

Treat patients using the C+ approach, which includes the zygomatic arch, jaw ramus, jawline, prejowl sulcus, and the submalar area. Utilize the three entry points located in the jowl, jaw angle, and jaw ramus to achieve full coverage of the treatment areas.

*The responses of N=82 physicians when asked what injection technique and how many entry points they would suggest experienced injectors use to treat patients with HArmonyCa® and a survey of N=80 physicians when asked, "What injection technique do you use when administering HArmonyCa® to a typical patient in your clinic?" and of N=76 physicians when asked, "When you inject HArmonyCa® posterior to the ligament line, how many injection entry points do you usually use in your clinical experience?"[19]

It is possible to use a TSK STERIGLIDE 22G cannula 50 mm in length in combination with a retrograde fanning technique to help distribute HArmonyCa® evenly into your patient's skin.

The C+ approach

Three entry points

- Jowl
- Jaw angle
- Jaw ramus

Contraindicated areas

When treating your patients with HArmonyCa®, avoid injecting it into any of the contraindicated facial areas.

Treatment considerations when injecting HArmonyCa®

Do not inject into:

- Glabellar area
- Periocular area
- Perioral region
- Lips

Please see HArmonyCa® DFU for the full list of AEs, contraindications, warnings, and precautions.


Glabellar area
Periocular area
Lips and
perioral region

"My skin texture is better, it looks better, and I feel more confident in myself." *Alan, 53*

Alan received a total of 5 mL of HArmonyCa® in the jaw and pre-auricular area. The model also received pre-treatment with a total of 6 mL of JUVÉDERM® products in the cheeks, chin, and jaw, during a separate treatment visit, one day prior to their "before" photo.

An integrated treatment approach

See the potential benefits of an integrated treatment approach with HArmonyCa®

HArmonyCa® is part of the Allergan Aesthetics advanced portfolio of high-quality products and support services designed to help make your patients' aesthetic aspirations a reality.[24]

HArmonyCa® may be used alongside other facial aesthetic treatments to give patients the natural-looking results they're looking for.*,†,‡,[3,19]

HArmonyCa®

JUVÉDERM®

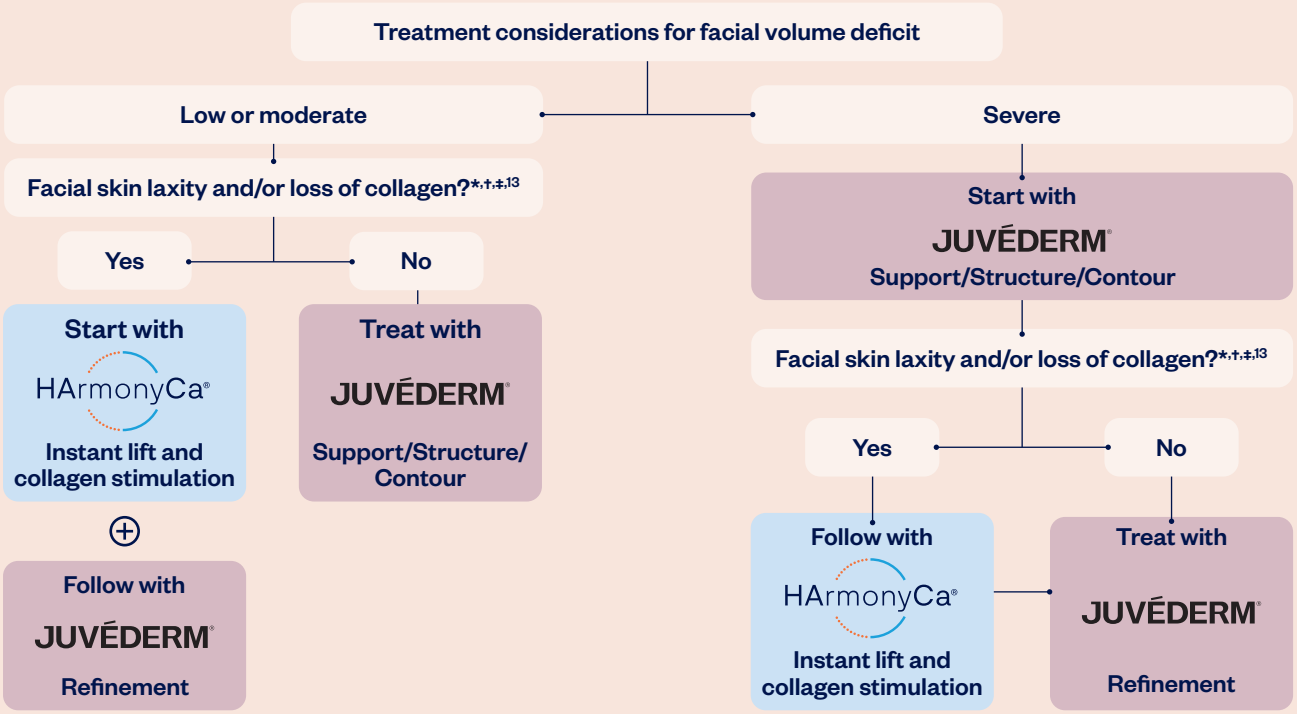
SKINVIVE™ BY JUVÉDERM™

BOTOX® Cosmetic (onabotulinumtoxinA for injection)

SKINMEDICA®

*The safety and efficacy of HArmonyCa® has not been evaluated in patients treated with other treatments.[3]
†Please see HArmonyCa® DFU for the full list of contraindications, warnings, and precautions.
‡Based on a survey of N=70 physicians when asked, "In your experience, do you combine other technologies to your treatment plans with HArmonyCa®?"[19]

Integrating HArmonyCa® and JUVÉDERM®



Treatment areas:[19]
- Zygomatic arch
- Jaw ramus
- Jawline
- Submalar area
- Pre-jowl sulcus

Injection depth:[19]
Subcutaneous with fanning technique

Treatment areas:[25,26]
- Nasolabial fold – VOLIFT®
- Lips – VOLBELLA®
- Tear trough – VOLBELLA®

Treatment areas:[25,27,28]
- Midface – VOLUMA® and/or VOLIFT®
- Lower face – VOLUX™ and/or VOLUMA®

The safety and efficacy of HArmonyCa® has not been evaluated in patients treated with other filling implants.

There is no data available regarding the safety of injecting a greater amount than 20 mL of ALLERGAN dermal fillers per 60 kg body mass per year.

The responsibility of treatment decisions remains with the treating healthcare professional. Treatment planning should be based on individual needs.

Please refer to the Directions for Use for the use of each product.

*Results from a prospective and non-randomized interventional study where HArmonyCa® was injected in the pre-auricular region of 15 women. The primary endpoint was the volumetric changes at Day 180. Secondary endpoints included changes in facial tension vectors, time to filler tissue integration, and safety profile.[13]

†Ultrasound and elastography examinations were performed using the Samsung HT 30 ultrasound machine and the ElastoScan HS30/XH30, respectively (Samsung Healthcare Global). When compared to baseline, an increase in density, viscoelasticity, and firmness of the tissue was observed at 60 days and then confirmed at 90 days after treatment. At 180 days after treatment, an increase in collagen in the treated areas was confirmed.[13]

‡Vectra® H2 (Canfield Scientific, Inc.) was used to assess skin lift and tightening by measuring the changes in FTV at 60, 90, and 180 days after treatment. As compared to pre-treatment values, FTV significantly increased at all timepoints with a median (interquartile range) increase of 2.2 (1.6– 2.2) mm and 2.0 (1.7–2.2) mm in the right and left side, respectively (p<0.0001 each), 180 days after treatment.[13]

HArmonyCa® and Juvéderm® VYCROSS® collection: gel properties and characteristics

	HArmonyCa® Lidocaine	SKINVIVE™ by Juvéderm®	Juvéderm® VOLBELLA® with lidocaine
HA CONCENTRATION (mg/mL) + 3.0 mg lidocaine[3,25-29]	20	12	15
EXTRUSION FORCE at 50 mm/min (N)*[,30,31]	27G 1/2" needle 30.0	32G 1/2" needle 19.7	32G 1/2" needle 28.0
COHESIVITY (grams-force)†[,32,33]	58	12	19
ELASTICITY (G' at 5 Hz, pascals)†[,32,33]	644	166	271
LIFT CAPACITY‡[,8,34]			

Juvéderm® VOLIFT® with lidocaine	Juvéderm® VOLUMA® with lidocaine	Juvéderm® VOLUX™
17.5	20	25
30G 1/2" needle 18.6	27G 1/2" needle 15.8	27G 1/2" needle 16.5
30	40	93
340	398	665

Images are for illustrative purposes only and are not an accurate representation of the data.
Maximum and minimum parameters set relative to HArmonyCa® Lidocaine Dual-Action Injectable and JUVÉDERM® facial fillers with the highest and lowest values for gel property/rheological characteristic/measure across HArmonyCa® and the entire JUVÉDERM® collection, respectively.

*The method for measuring the extrusion force (N) was performed at a fixed rate of 50 mm/min.[30,31] The extrusion force of gels is a characteristic to describe their physical responses to applied forces upon injection and should not be individually translated into clinical performance.[30,31]
†The rheological properties of gels are characteristics to describe their physical responses to applied forces in vitro and should not be individually translated to clinical performance.[29,30]
‡Results from a pre-clinical animal study of HArmonyCa®, with results demonstrated over 12 weeks, showed that HArmonyCa® led to an instant and sustained lift following injection.[8]

Treatment considerations to help your patients reach their aesthetic goals

After treating your patient with HArmonyCa®

- If your patient requires further refinements with HA-only fillers, JUVÉDERM® products may be used. This can occur at the same visit or after 0 to 6 months, depending on individual needs of your patient*[,19]

HArmonyCa® retreatment

- Additional HArmonyCa® treatment can be administered at any time after 6 months†[,19]

Other treatments with HArmonyCa®

- Allow at least 4 weeks between ultrasound-based, laser, or peeling treatments and the use of HArmonyCa®[3]

*Based on a survey of N=62 physicians when asked, "In your experience, do you inject HArmonyCa® and JUVÉDERM® in the same session?" and on a survey of N=66 physicians when asked, "What is the interval between HArmonyCa® and JUVÉDERM® treatments (if not at the same session)?"[19]

†Based on a survey of N=67 physicians when asked, "Based on your experience with the performance of HArmonyCa® and patient needs, what interval do you usually leave between HArmonyCa® treatments?"[19]

Help to achieve their aesthetic aspirations with HArmonyCa®

A dual-action injectable

- HArmonyCa® improves skin architecture by providing long-lasting lift and sustained collagen stimulation to enhance skin density and elasticity.*,†,[35]

The HArmonyCa® injection technique

- The recommended C/C+ injection technique may help your patients achieve a desired result when using HArmonyCa®.[19]

An integrated treatment approach

- Help your suitable patients reach their aesthetic goals with a treatment plan which integrates HArmonyCa® and the JUVÉDERM® range.

IHC: immunohistochemistry; FISH: fluorescent in situ hybridization; ECM: extracellular matrix

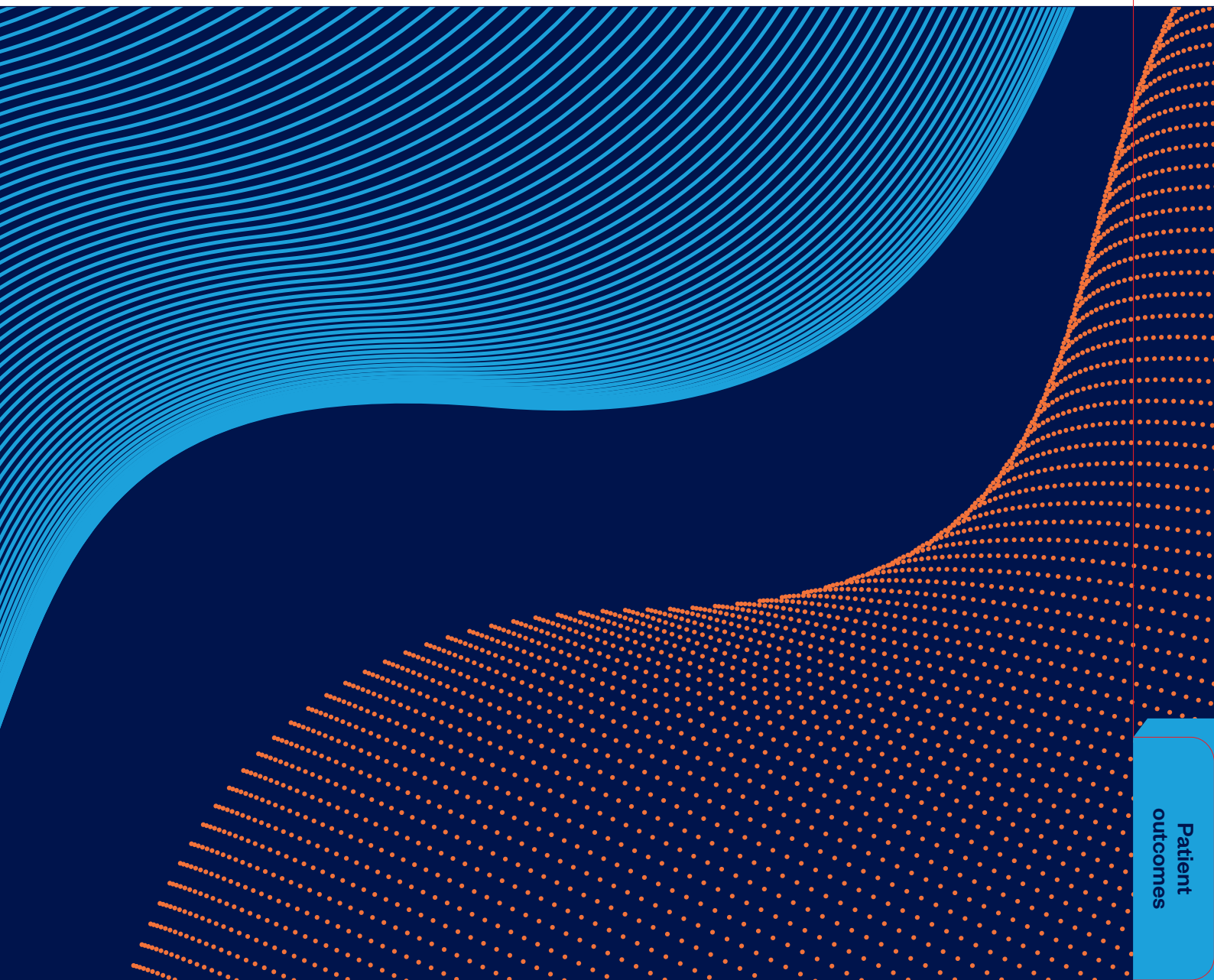
*Results from a rat model study to evaluate and compare the stimulatory effects of HArmonyCa® and Radiesse® in vivo. Integrated analysis (proteomics, IHC, FISH, and image analysis techniques) was performed on rat skin samples 1, 8, and 26 weeks after subcutaneous injection. 8 samples were prepared for each filler.[35]

†Preclinical proteomic analysis indicated upregulation of the ECM proteoglycans pathway at Week 1 in HArmonyCa®, with biglycan (Bgn) specifically upregulated compared to Radiesse®. No significant differences were observed between HArmonyCa® and Radiesse® at Weeks 8 and 26. Additional ECM proteoglycans were detected, including lumican and versican, with no significant difference between HArmonyCa® and Radiesse® at each timepoint.[35]

"I would definitely consider having the HArmonyCa® treatment again." *Claire, 50*

Claire, received a total of 5 mL of HArmonyCa® in the cheeks, jaw, and pre-auricular area. Claire also received pre-treatment with BOTOX COSMETIC® (botulinum toxin type A) and a total of 6 mL of JUVÉDERM® products, in the cheeks, jaw, nasolabial folds, and tear trough during a separate treatment visit 11 days prior to their "before" photo.

Patient outcomes



Before and after: patient photos and testimonials

Meet Alan

"I feel confident with the way I look at the moment. I mean, before, my jawline blended in with my neck, but now I've got more shape to it. So, I'm really pleased with it, and I feel so much more confident." – *Alan, 53*

Meet Debbie

"You feel slightly more rejuvenated almost not just in your face, but in your body. It gives you a lighter, maybe a happier feel. Yeah, it just gives you a certain little confidence, I think, that you just look and feel better." – *Debbie, 54*

Patient outcomes

Individual results may vary. Patients received free treatment and follow-up, payment for their participation and their expenses were covered. Their photo was taken before HArmonyCa® injection. Our model, Alan, received a total of 5 mL of HArmonyCa® in the jaw and pre-auricular area. Alan also received pre-treatment with a total of 6 mL of JUVÉDERM® products in the cheeks, chin, and jaw, during a separate treatment visit, one day prior to their "before" photo. Our model, Debbie, received a total of 5.9 mL of HArmonyCa® in the jaw and pre-auricular area and cheeks. Debbie also received pre-treatment with BOTOX COSMETIC® (botulinum toxin type A) and a total of 2 mL JUVÉDERM® products in the cheeks during a separate treatment visit, 17 days prior to their "before" photo.

Reveal a refreshed, rested, and youthful look that patients are highly satisfied with[11,13]

HArmonyCa® visibly improves overall appearance for more than 90% of patients.*,†,[2]

Throughout a 1-year clinical study (N=140), **more than 90% of patients saw ongoing visible improvements in their overall facial appearance**, which was also validated by investigators*,†,[2]

- 91.8% of patients reported an overall aesthetic improvement at 1 month, and 72.6% at 1 year
- Investigators reported that approximately 98.5% of patients had an overall aesthetic improvement at 1 month, and 75.6% at 1 year

*Results from a 1-year, prospective, open-label, post-marketing study where HArmonyCa® and HArmonyCa® Lidocaine were injected in the midface of 140 patients with moderate to severe midface volume deficit. The primary endpoint was responder status based on EI-assessed MFVDS at Month 1. Secondary endpoints included responder status based on EI-assessed and participant-assessed GAIS, change from baseline on FACE-Q Satisfaction with Cheeks questionnaire, and change from baseline on FACE-Q Satisfaction with Facial Appearance questionnaire. The mITT population was all treated participants with non-missing baseline MFVDS score. At Month 1, the MFVDS responder status (a participant with at least a 1-grade improvement on the MFVDS based on the EI's live assessment of midface volume deficit) was 82.8% (95% CI: 75.7%–88.5%) in the mITT population for both treatment groups combined.[2]

†The EI-assessed GAIS responder rate (improved or much improved) was 98.5% (132/134) at Month 1, 98.5% (130/132) at Month 3, 94.7% (126/133) at Month 6, 87.8% (115/131) at Month 9, and 75.6% (102/135) at Month 12. The participant-assessed GAIS responder rate (improved or much improved) was 91.8% (123/134) at Month 1, 86.4% (114/132) at Month 3, 81.2% (108/133) at Month 6, 75.4% (98/130) at Month 9, and 72.6% (98/135) at Month 12.[2]

Safety information

HArmonyCa® safety information

HArmonyCa® injection may be accompanied with mild discomfort; administration of anesthetics should be considered. As with all transcutaneous procedures, injection of HArmonyCa® carries a risk of infection. To reduce this risk, common practice of such procedures should be followed. If nodules appear, patient should massage the treated area. Patient should be informed that the injected material may be palpable for a long period after treatment. Common postoperative adverse events include erythema, edema (swelling), pain, tenderness, and itching. Treatment site reactions typically resolve within 24–48 hours and swelling within a week. Less common adverse events associated with dermal fillers in general and calcium hydroxyapatite-based fillers in particular include hematoma, seroma, extrusion, induration, skin pigmentation, fistula formation, inflammatory reaction, infection, allergic reaction, migration, persistent nodules, granulomas, fever, necrosis, and blindness.

BOTOX COSMETIC® safety information

BOTOX COSMETIC® is used to treat upper facial rhytides, including forehead, lateral canthus, glabellar lines, and for the improvement in the appearance of platysma prominence in adults.

Serious Warnings and Precautions

- The term "Allergan Unit" upon which dosing is based is a specific measurement of toxin activity that is unique to this formulation of botulinum toxin type A. Therefore, the "Allergan Units" used to describe BOTOX® and BOTOX COSMETIC®'s activity are different from those used to describe that of other botulinum toxin preparations and the units representing BOTOX® and BOTOX COSMETIC®'s activity are not interchangeable with other products.
- BOTOX COSMETIC® should only be given by a physician or authorized prescriber with the appropriate qualifications and experience in the treatment and the use of required equipment.
- Follow the recommended dosage and frequency of administration for BOTOX COSMETIC®.
- DISTANT SPREAD OF TOXIN EFFECT: The effects of BOTOX COSMETIC® and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life-threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity, but symptoms can occur in adults, particularly in those patients who have underlying conditions that would predispose them to these symptoms.

General

- BOTOX® and BOTOX COSMETIC® contain the same active ingredient in the same formulation. Therefore, adverse events observed with the use of BOTOX® also have the potential to be associated with the use of BOTOX COSMETIC®.
- Use BOTOX COSMETIC® only as directed.
- Do not use dosage recommendations and potency Units applied to other botulinum toxin products when using BOTOX COSMETIC®.
- The safe and effective use of BOTOX COSMETIC® depends upon proper storage of the product, selection of the correct dose, and proper reconstitution and administration techniques.

- A physician or authorized prescriber administering BOTOX COSMETIC® should be familiar with the relevant anatomy of the area involved and any alterations to the anatomy due to prior surgical procedures. Care should be taken when injecting in or near vulnerable anatomic structures. Serious adverse events including fatal outcomes have been reported in patients who had received BOTOX COSMETIC® injected directly into salivary glands, the oro-lingual-pharyngeal region, esophagus, and stomach. Some patients had pre-existing dysphagia or significant debility. Pneumothorax associated with injection procedure has been reported following the administration of BOTOX COSMETIC® near the thorax. Caution is warranted when injecting in proximity to the lung, particularly the apices.
- Caution should be used when BOTOX COSMETIC® is used in the presence of inflammation at the proposed injection site(s) or when excessive weakness or atrophy is present in the target muscle.
- Local muscle weakness represents the expected pharmacological action of botulinum toxin in muscle tissue. However, weakness of adjacent muscles associated with local diffusion and/or injection technique has been reported.
- Progressive signs or symptoms of muscular weakness remote to the site of injection may include ptosis and diplopia, as well as other serious adverse effects including swallowing and speech disorders, generalized weakness, or respiratory failure. In addition, certain adverse effects (e.g. dysphagia, aspiration pneumonia) have been rarely reported in both pediatric and adult patients, some of which have been associated with a fatal outcome.
- Asthenia, muscle weakness, dizziness, and visual disturbance have been reported after treatment of BOTOX® and/or BOTOX COSMETIC® and could make driving or using machines dangerous.
- When exposed to very high doses, patients with neurologic disorders, e.g. pediatric cerebral palsy or adult spasticity, may be at increased risk of clinically significant systemic effects.
- Patients or caregivers should be advised to seek immediate medical care if swallowing, speech, or respiratory disorders arise.
- Patients with a history of underlying neurologic disorders, dysphagia, and/or aspiration should be treated with extreme caution. The botulinum toxin product should be used under specialist supervision in these patients and should only be used if the benefit of treatment is considered to outweigh the risk.
- Injection intervals of BOTOX COSMETIC® should be no more frequent than every three months. Indication-specific dosage and administration recommendations should be followed. If combined with non-cosmetic indications, the maximum cumulative dose in a 3-month interval should generally not exceed 6 Units/kg or 360 Units, whichever is lower.
- The primary release procedure for BOTOX COSMETIC® uses a cell-based potency assay to determine the potency relative to a reference standard. The assay is specific to AbbVie's product BOTOX COSMETIC®. One Allergan Unit corresponds to the calculated median intraperitoneal lethal dose (LD50) in mice. Due to specific details of this assay such as the vehicle, dilution scheme, and laboratory protocols, Units of biological activity of BOTOX COSMETIC® cannot be compared to nor converted into Units of any other botulinum toxin or any toxin assessed with any other specific assay method. The specific activity of BOTOX COSMETIC® is approximately 20 Units/nanogram of neurotoxin protein complex.
- This product contains human serum albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) also is considered extremely remote. No cases of transmission of viral diseases or CJD have ever been identified for albumin.

For More Information

Please consult the Product Monograph available at www.abbvie.ca for important information relating to adverse reactions, drug interactions (particularly aminoglycosides or neuromuscular blocking agents), and dosing information which have not been discussed in this piece.
The Product Monograph is also available by calling us at 1-800-668-6424.

References

1. Data on file. DART trademark. Allergan Pharmaceuticals. October 28, 2025.
2. Gritti A, et al. *J Cosmet Dermatol*. 2025;24(9):e70430.
3. Allergan Aesthetics. HArmonyCa® Lidocaine DFU. November 14, 2025.
4. Hee C, et al. *Dermatol Surg*. 2015;41:S373–381.
5. Segal T, et al. *Kosmetische Medizin*. 2014;1.16:22–27.
6. Berlin A, et al. *Dermatol Surg*. 2008;34(1 Suppl):S64–67.
7. Gonzaga da Cunha M, et al. *Surg Cosmet Dermatol*. 2020;12:109–117.
8. Allergan Aesthetics. Data on file. HArmonyCa® Lidocaine ABVRRTI80007. Lift capacity. October 2023. REF-84448.
9. Merz. Radiesse® Instructions for Use. EM00543-04/JAN 2016
10. Braz A, et al. *Plast Reconstr Surg Glob Open*. 2024;12(2):e5622.
11. Allergan Aesthetics. Data on file. HArmonyCa® Lidocaine. Clinical Study Report. July 2022. REF-99624.
12. Allergan Aesthetics. Data on file. HArmonyCa® Susceptibility to Hyaluronidase. October 2023. REF-98651.
13. Urdiales-Gálvez F, et al. *J Cosmet Dermatol*. 2023;22(8):2186–2197.
14. Swift A, et al. *Aesthet Surg J*. 2021;41(10):1107–1119.
15. Heusèle C, et al. Chapter 24. Lips and Lipsticks. In: Draelos Z, ed. Cosmetic Dermatology: Products & Procedures. 1st ed. Wiley-Blackwell, 2010. p. 184–189. ISBN 978-1-4051-8635-3.
16. Wulc AE, et al. Chapter 2. The Anatomic Basis of Midfacial Aging. In: Hartstein ME, et al. eds. Midfacial Rejuvenation. 1st ed. Springer, 2012. p. 15–28. ISBN 978-1-4614-1006-5.
17. Coleman SR, and Grover R. *Aesthet Surg J*. 2006;26(1S):S4–9.
18. Kaur M, et al. *Egypt J Forensic Sci*. 2014;5:46–56.
19. Allergan Aesthetics. Data on file. HArmonyCa® Lidocaine – Train-the-trainer meeting 2022: Reported outputs. August 2023. REF-114077.
20. Goldie K, et al. *Clin Cosmet Investig Dermatol*. 2021;14:643–654.
21. Swamy R, and Sam P. *Facial Plast Surg Clin North Am*. 2010;18(2):245–252.
22. Linming F, et al. *Skin Res Technol*. 2018;24(1):3–8.
23. Ohshima H, et al. *Skin Res Technol*. 2013;19:e238–e242.
24. Allergan Aesthetics – Science – Pipeline. Available from: https://global. allerganaesthetics.com/. Accessed January 2026.
25. Allergan Aesthetics. Juvéderm® VOLIFT® Lidocaine DFU. June 28, 2019.
26. Allergan Aesthetics. Juvéderm® VOLBELLA® Lidocaine DFU. October 26, 2018.
27. Allergan Aesthetics. Juvéderm® VOLUMA® Lidocaine DFU. June 12, 2018.
28. Allergan Aesthetics. Juvéderm® VOLUX™ Lidocaine DFU. February 12, 2019.
29. Allergan Aesthetics. SKINVIVE™ by Juvéderm DFU. September 30, 2022.
30. Allergan Aesthetics. Data on file. ABVRRTI80046 HArmonyCa® Lidocaine Extrusion Force. REF-84449.
31. Allergan Aesthetics. Data on file. ABVRRTI77295 Juvéderm Extrusion Force Data. REF-89667.
32. Allergan Aesthetics. Data on file. ABVRRTI80048 HArmonyCa® Lidocaine Rheology: Elasticity and Cohesivity. REF-84447.
33. de la Guardia C, et al. *Facial Plast Surg*. 2022;38(2):116–123.
34. Allergan Aesthetics. Data on file. ABVRRTI80027 Juvéderm® VYCROSS Collection Lift Capacity. REF-80817.
35. Allergan Aesthetics. Data on file. ABVRRTI81261 Comparative Analysis of Bio-Stimulatory Effects. REF-139077.

HArmonyCa®

Allergan Aesthetics
an AbbVie company