

saypha®

croma



VOLUMISING WITH COMFORT

MDR* approved, aesthetic dermal filler

*Medical Device Regulation

Product information for
healthcare professionals

saypha[®] volume

Lidocaine



saypha[®] volume Lidocaine is a cross-linked hyaluronic acid dermal filler indicated to correct moderate to severe nasolabial folds (NLFs).¹ The incorporated lidocaine, facilitates enhanced treatment comfort for patients.^{1,2}

Product specifications¹

Concentration HA	2.3 %
Crosslinking agent	BDDE (concentration ≤ 2 ppm)
Additional ingredients	0.79% sodium chloride, 0.24% disodium phosphate dodecahydrate, 0.05% sodium dihydrogen phosphate dihydrate, 0.3% lidocaine HCL (as anaesthetic), pH of 6.7-7.3
Crosslinking degree	0.5-1.5 %
Particle size	$\sim 325 \mu\text{m}$
Injection depth	Deep dermis, subcutis or supraperiosteal tissue
Needle	27 G x 1/2" thin wall Terumo [™] needle (CE 0197)
Packaging unit	1 box of 1 mL syringe
Indication	The viscoelastic implant is indicated to correct moderate to severe nasolabial folds.

Comfort Flow syringe

Designed for optimal and reliable handling.³

PREMIUM GLASS SYRINGE

**NEW PRIMARY LABEL:
EASY READABLE SCALE**

**CLEAR DIFFERENTIATION:
NEW COLOUR CODING FOR EVERY
PRODUCT**

**DEVELOPED AND TESTED TOGETHER
WITH HEALTHCARE PROFESSIONALS³**



Extrusion force

With a keen focus on every detail, the optimised HA fillers manufacturing process and meticulously designed syringe, ensure reliable extrusion force of saypha® products. **saypha® volume Lidocaine shows a comparable extrusion force among other competitors on the market.**⁴

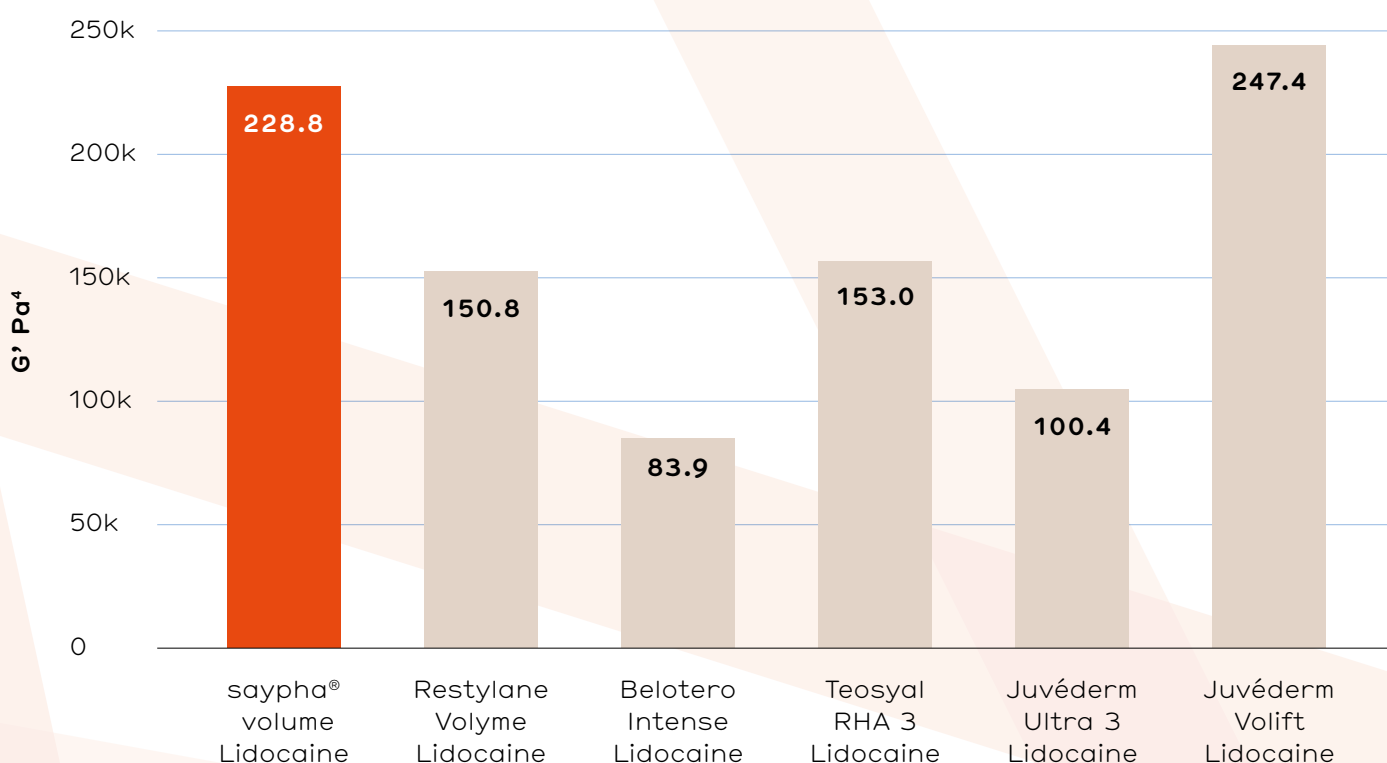
Product	IF [N]
saypha® volume Lidocaine	14
Restylane Volyme Lidocaine	14
Belotero Intense Lidocaine	23
Teosyal RHA 3 Lidocaine	12
Juvéderm Ultra 3 Lidocaine	10
Juvéderm Volift Lidocaine	6

*all products were tested with 27G x 1/2" needles

Rheology Data

G' (G prime)

G' reflects the ability of the gel to regain its original shape after deformation.⁵ It is an indicator for the lifting and volumising capacities of HA fillers.^{5,6,7}



saypha[®] volume

Lidocaine

Clinically proven effectiveness & safety

for correction of **nasolabial folds**⁸

A prospective, open-label, multicentre, post-market study was performed to **evaluate safety and efficacy** of saypha[®] volume Lidocaine over **36 weeks** in **62 adult women and men** for the correction of **nasolabial folds** (NLFs).

Month 1

95% of the patients showed improvement^{a,8}

Month 6

95% of the patients showed improvement^{a,8}

Month 9

87% of the patients showed improvement^{b,8}

93.5% patient satisfaction rate^{c,8} and aesthetic improvement^{d,8}



Mild adverse events – mainly attributed to injection site reaction.⁸

a. by ≥ 1 grade on the NLF-SRS vs baseline, with 95.1% of subjects showing an improvement of at least 1 grade of the NLF-SRS at 4 and 24 weeks after the treatment, the primary endpoint was achieved, and clinical performance was demonstrated. b. by ≥ 1 grade on the NLF-SRS vs baseline. c. at week 36 79.0% very satisfied subjects, and 14.5% satisfied subjects. d. Based on the investigator-assessed GAIS score, the NLFs had improved (corresponding to a score < 4) in 100% of subjects at Week 4, in 95.1% at Week 24, and in 93.5% at Week 36.

Clinical benefits

A close-up portrait of a woman with dark hair and green eyes. Two hands are holding orange ampoules of Saypha Volume Lidocaine. One ampoule is held horizontally across her forehead, and the other is held diagonally across her cheek. The background is a solid orange color.

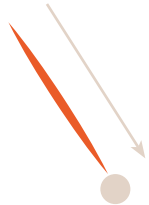
SAYPHA® VOLUME LIDOCAINE IS DESIGNED FOR APPLICATION WITH **NEEDLE OR CANNULA**.¹

SAYPHA® VOLUME LIDOCAINE PRIORITISES **PATIENT COMFORT**^{1,2} AND **SATISFYING TREATMENT EXPERIENCE**.⁸

THE FILLING EFFECT OF SAYPHA® VOLUME LIDOCAINE LASTS UP TO **9 MONTHS** AFTER THE TREATMENT.^{1,8}

Artful Accuracy

Injection techniques for the correction of nasolabial folds.¹



- **Retrograde injection**

- » Introduction of the entire needle/cannula along the fold or skin depression and injecting while slowly withdrawing the needle/cannula.⁹
- » Deep dermis, subcutis or supraperiosteal tissue.¹



- **Bolus technique**

- » The vertical supraperiosteal depot technique, where small depots of the filler (0.02-0.05 mL) were placed via serial vertical injections (2-3 mm apart) directly on the periosteum.⁹
- » Deep dermis, subcutis or supraperiosteal tissue.¹



- **Fan technique**

- » The fan technique consists in introducing the needle/cannula as for the retrograde technique, and injecting the gel while withdrawing the needle/cannula, without removing its tip from the skin; then, changing the direction of the needle and injecting a new line.¹⁰
- » Deep dermis, subcutis or supraperiosteal tissue.¹



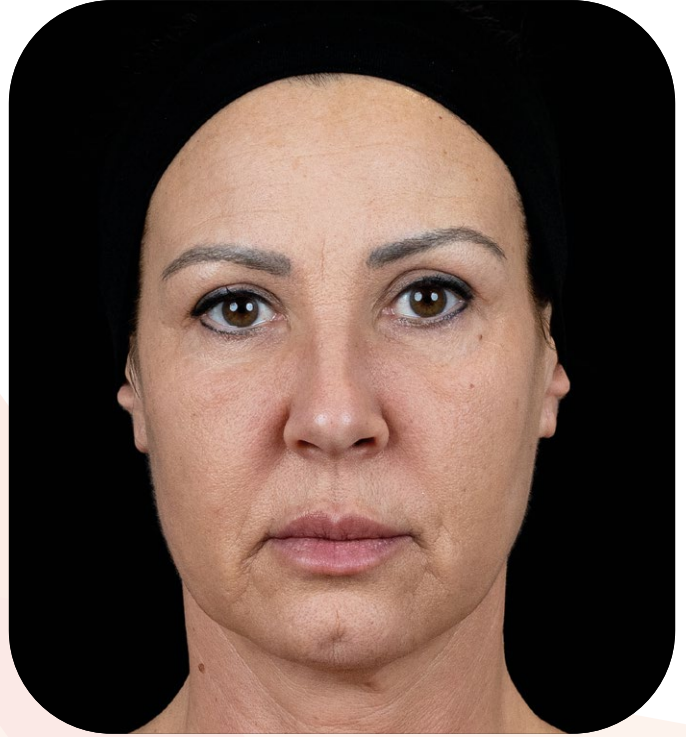
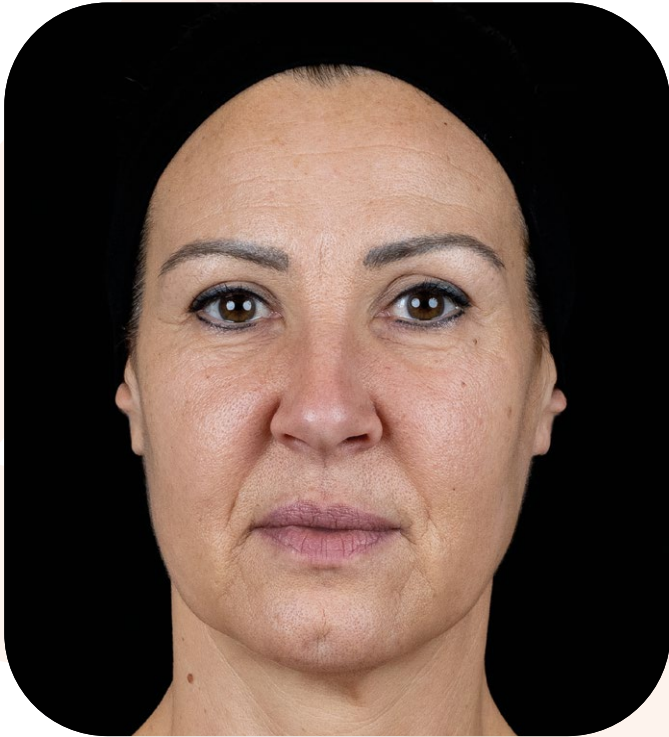
- **Serial-threading technique**

- » Introduction of the entire needle/cannula along the wrinkle or skin depression and injecting while slowly withdrawing the needle/cannula.⁹ The product should be placed in several linear threads.
- » Deep dermis, subcutis or supraperiosteal tissue.¹

Real Results



Patient received saypha® volume Lidocaine for the correction of nasolabial folds with retrograde serial linear threading technique into the deep dermis. 0.7 ml in total for 2 sides.



Patient treated with saypha® volume Lidocaine for the correction of nasolabial folds with retrograde serial linear threading into the deep dermis. 0.7ml in total for 2 sides.



saypha® rich



saypha® filler



saypha® filler Lidocaine



saypha® volume



saypha® volume Lidocaine



saypha® volume plus Lidocaine

References

- 1 Instruction for use (IFU)
- 2 Levy PM, De Boule K, Raspaldo H. Comparison of injection comfort of a new category of cohesive hyaluronic acid filler with preincorporated lidocaine and a hyaluronic acid filler alone. *Dermatol Surg.* 2009 Feb;35 Suppl 1:332-6; discussion 337. doi: 10.1111/j.1524-4725.2008.01045.x. PMID: 19207322
- 3 Syringe design award <https://ifdesign.com/en/winner-ranking/project/quatroject/203634>
- 4 Data on File
- 5 de la Guardia C, Virno A, Musumeci M, Bernardin A, Silberberg MB. Rheologic and Physicochemical Characteristics of Hyaluronic Acid Fillers: Overview and Relationship to Product Performance. *Facial Plast Surg.* 2022 Apr;38(2):116-123. doi: 10.1055/s-0041-1741560. Epub 2022 Feb 3. PMID: 35114708; PMCID: 35114708
- 6 Fundarò SP, Salti G, Malgapo DMH, Innocenti S. The Rheology and Physicochemical Characteristics of Hyaluronic Acid Fillers: Their Clinical Implications. *Int J Mol Sci.* 2022 Sep 10;23(18):10518. doi: 10.3390/ijms231810518. PMID: 36142430; PMCID: PMC9503994.
- 7 Stocks D, Sundaram H, Michaels J, Durrani MJ, Wortzman MS, Nelson DB. Rheological evaluation of the physical properties of hyaluronic acid dermal fillers. *J Drugs Dermatol.* 2011 Sep;10(9):974-80. PMID: 22052265.
- 8 Kopera D, Ivezic-Schoenfeld Z, Chang-Rodriguez S, Hoeller S, Grablowitz D, Bartsch K, Prinz M. A prospective, open label, multicenter, postmarket study evaluating Princess volume Lidocaine for the correction of nasolabial folds. *Dermatol Ther.* 2020 Nov;33(6):e14310. doi: 10.1111/dth.14310. Epub 2020 Oct 5. PMID: 3294616 (Since 2018 the product range is named saypha®)
- 9 Data on File
- 10 Data on File

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