saypha®

croma

FILLING WITH COMFORT

MDR* approved, aesthetic dermal filler

*Medical Device Regulation

Product information for healthcare professionals

saypha® filler

Lidocaine

saypha® filler Lidocaine is a cross-linked hyaluronic acid dermal filler indicated to correct moderate to severe nasolabial folds and lip augmentation.[1] The incorporated Lidocaine, faciliates enhanced treatment comfort for your patients.[1,2]

Product specifications[1]

Concentration HA	2.3%
Crosslinking agent	BDDE (concentration ≤ 2 ppm)
Additional ingredients	0.75% 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	0.5-1.0%
Particle size	~ 316 µm
Injection depth	Mid to deep dermis or submucosa
Needle	27 G x ½" 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 and for lip augmentation.

Comfort Flow syringe

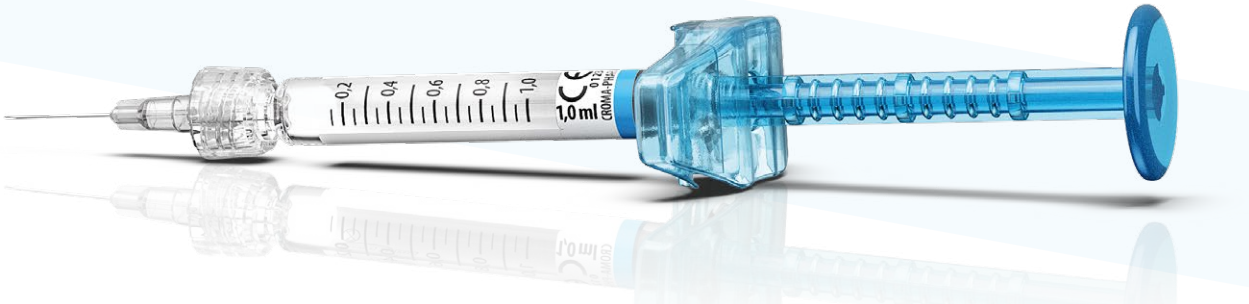
Designed for optimal and reliable handling.[3]

PREMIUM GLASS SYRINGE

NEW PRIMARY LABEL: EASY READABLE SCALE

CLEAR DIFFERENTIATION: NEW COLOUR CODING FOR EVERY PRODUCT

DEVELOPED AND TESTED TOGETHER WITH HEALTHCARE PROFESSIONALS[3]



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® filler Lidocaine shows a constantly comparable extrusion force**[4]

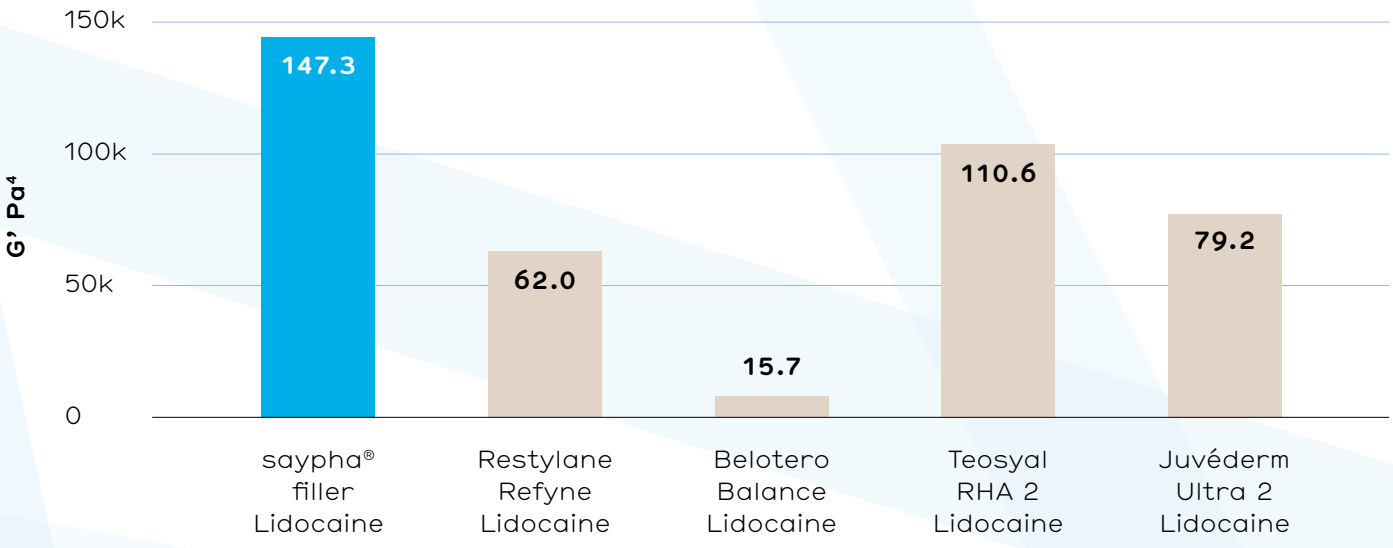
Product	IF [N]
saypha® filler Lidocaine	12
Restylane Refyne Lidocaine	10
Belotero Balance Lidocaine	10
Teosyal RHA 2 Lidocaine	11
Juvéderm Ultra 2 Lidocaine	9

* all products were tested with 27G x ½" needles

Rheology Data

G' (G prime)

A high G' is one of the main parameters that influences the lifting[5] and volumising[6,7] capacities of HA fillers. saypha® filler Lidocaine was developed with a lower G' within saypha® portfolio, specifically for targeted application to correct moderate to severe facial nasolabial folds and for lip augmentation.[1,8]



saypha®
filler
Lidocaine

Clinically proven effectiveness & safety

for the correction of **nasolabial folds**[9]

A prospective, open-label, multicentre, post-market study to evaluate **safety and efficacy** of saypha® filler Lidocaine over **36 weeks** in **60 adult women and men** for the **correction of nasolabial folds** (NLFs).

Month 1

Almost all the subjects demonstrated improvement of NFLs[a,1,9]

Month 6

Almost all the subjects demonstrated aesthetic improvement[b,9]

Month 9

93% of the subjects were still “satisfied” or “very satisfied”[c,9]

97% of the patients demonstrated improvement of NFLs[a,1,9]

Adverse device effects (ADEs) were mild or moderate[d,9]

a. Out of 60 analysed subjects, 59 (98.3%) had improved their NLF severity by at least 1 grade on the NLF-SRS (Nasolabial Fold Severity Rating Scale) at week 4, 58 subjects (96.7%) at weeks 24 and 36 based on investigators´ evaluation. b. 59 evaluated subjects (98.3%) had improved aesthetics (below score 4 of the GAIS) at week 4 and week 24. c. 56 of 60 subjects (93.3%) were very satisfied or satisfied with the treatment 36 weeks post-initial treatment. d. Adverse device events (ADEs) were mild or moderate and resolved at least 25 days post-onset.

Clinical benefits

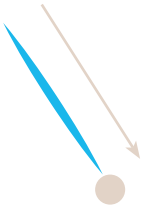
THE LASTING IMPACT OF SATISFACTION[c]
ENDURING FOR 9 OUT OF 10 TREATED PATIENTS EVEN 9 MONTHS AFTER TREATMENT.[9]

THE FILLING EFFECT FOR NASOLABIAL FOLDS LASTS UP TO 9 MONTHS.[a,1,9]

ENHANCED TREATMENT COMFORT
FACILITATED BY **LIDOCAINE** AND
THE EXPERTISE OF THE HCP.[1,2]

Artful Accuracy

Injection techniques for the correction of nasolabial folds.[1]



- **Retrograde injection**
  - » Introduction of the entire needle along the fold or skin depression and injecting while slowly withdrawing the needle[10]
  - » Mid to deep dermis[1]

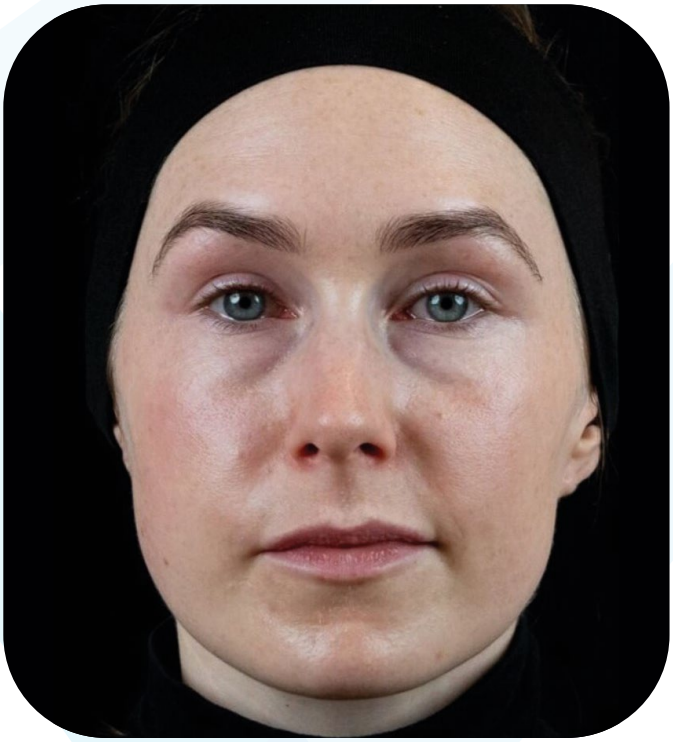
- **Bolus technique**
  - » Create a depot of filler deep at the centre of defect[11]
  - » Mid to deep dermis[1]

- **Fan technique**
  - » Fanning involves inserting the needle inferiorly on the fold and advancing it superiorly to the apex at the base of the nose[12] and placement of a row of linear threads, followed by an arc of linear threads emanating from a single injection point.[11]
  - » Mid to deep dermis[1]

- **Cross-hatching technique**
  - » Cross-hatching consists of a series of parallel linear threads injected at intervals of 5-10 mm followed by a new series of threads injected at right angles to the first set to form a grid.[13]
  - » Mid to deep dermis[1]

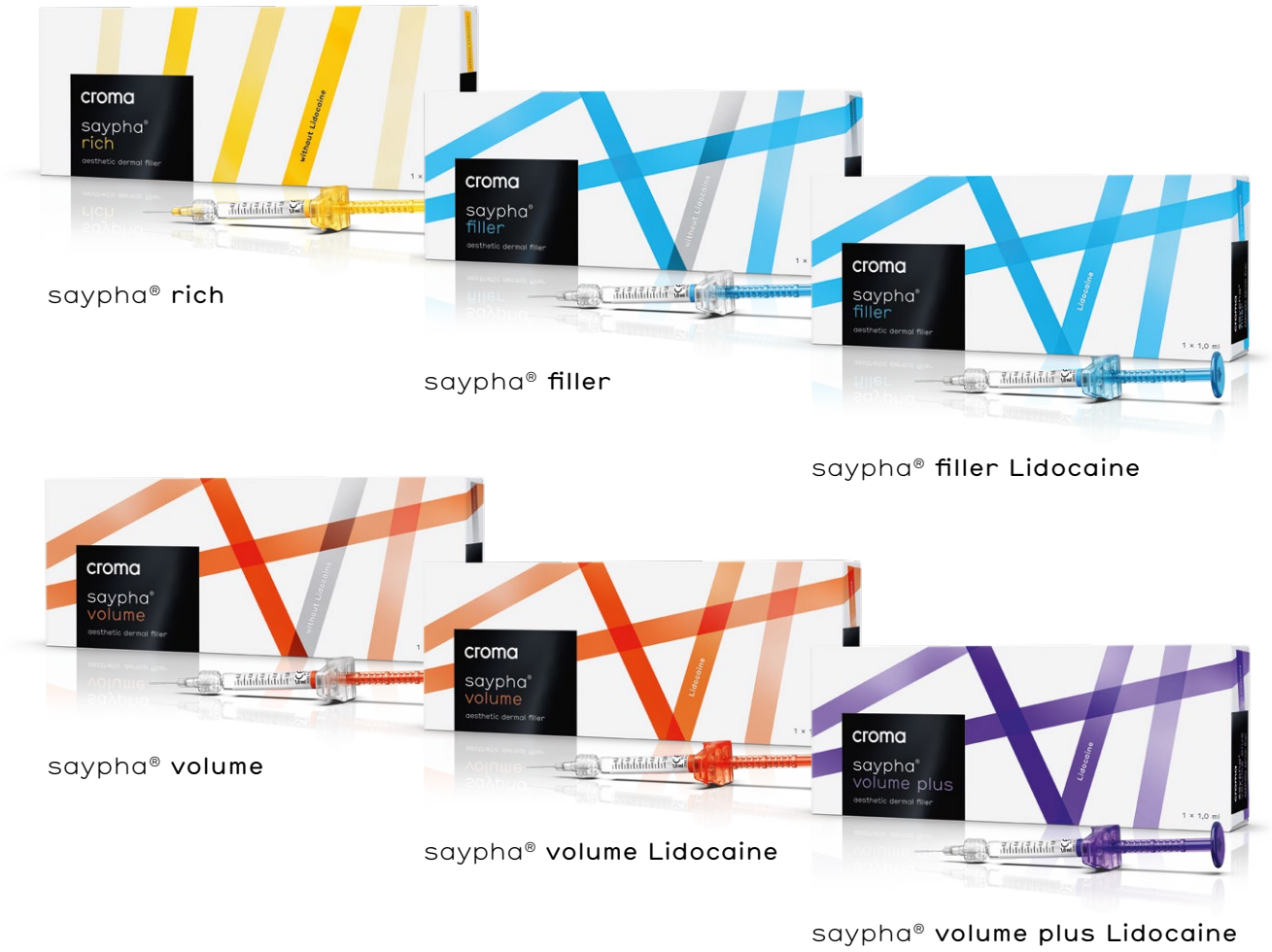
- **Serial puncture technique**
  - » Serial puncture comprises numerous small injections. Each injection perforates the dermis followed by extrusion of a droplet of filler material into the appropriate layer. The needle is then withdrawn and repositioned a small distance away; this process is then repeated.[11]
  - » Mid to deep dermis[1]

Real Results



Patient treated with saypha® filler Lidocaine for the correction of nasolabial folds with retrograde serial linear threading technique into the deep dermis. 0.2 mL per side.

Patient treated with saypha® filler Lidocaine for the correction of nasolabial folds with retrograde serial linear threading into the deep dermis. 0.5 mL per side.



References

1 Instruction for use (IFU)
2 Levy PM, De Boulle 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:
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 Data on file
9 Grablowitz D, Sulovsky M, Höller S, Ivezic-Schoenfeld Z, Chang-Rodriguez S, Prinz M. Safety And Efficacy Of Princess® filler Lidocaine In The Correction Of Nasolabial Folds. Clin Cosmet Investig Dermatol. 2019 Nov 26;12:857-864. doi: 10.2147/CCID.S211544. PMID: 31819583; PMCID: PMC6885652 (Since 2018 the product range is named saypha®).
10 Data on file
11 Data on file
12 Bass LS. Injectable Filler Techniques for Facial Rejuvenation, Volumization, and Augmentation. Facial Plast Surg Clin North Am. 2015 Nov;23(4):479-88. doi: 10.1016/j.fsc.2015.07.004. PMID: 26505544
13 Data on file

Austria - Headquarters

CROMA-PHARMA GmbH
Industriezeile 6
2100 Leobendorf
Austria
E-Mail: office@cromapharma.com

For more information visit

Croma-Pharma UK
T: +44 118 206 6513
Info.uk@cromapharma.com
www.cromapharma.com/uk
cromapharmauk

PBFILIDO0724GMX| 0924uk