

croma
For creators of beauty.

Croma Hyaluronic Acid Fillers

Croma syringe

Innovation for safety & comfort



Design excellence
developed and tested by experts¹
awarded with iF Design Award 2017

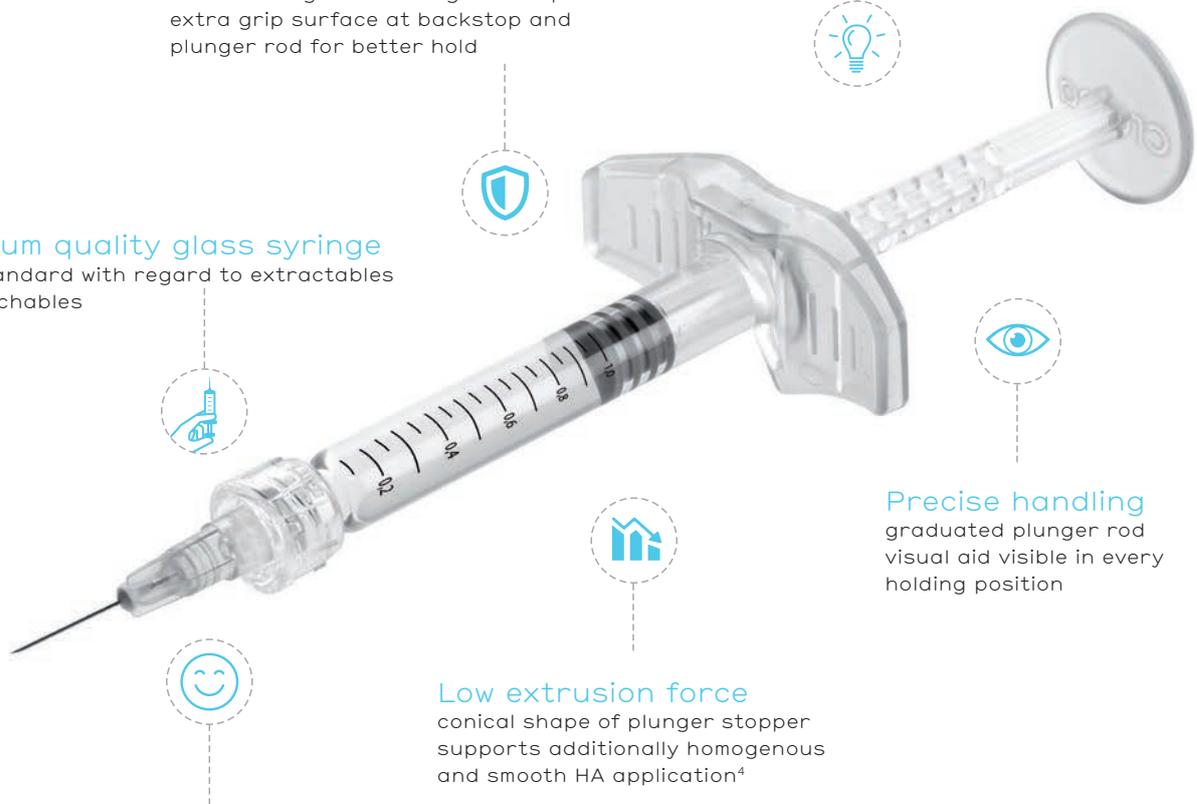
Safe application
solid and ergonomic designed components²
extra grip surface at backstop and
plunger rod for better hold

Premium quality glass syringe
gold standard with regard to extractables
and leachables

Precise handling
graduated plunger rod
visual aid visible in every
holding position

Low extrusion force
conical shape of plunger stopper
supports additionally homogenous
and smooth HA application⁴

High patient comfort
less bruising and side effects through thin
wall Terumo™ needles³



Extrusion force [N]

Product	EF [N]	Needle
Croma FILLER*	10	27G ½" thin wall Terumo™ (CE 0197)
Croma VOLUME*	12	

A low extrusion force is beneficial for smooth and predictable injections.

Croma FILLER can be easily injected when using a 27G ½" thin wall needle.

*available with/without lidocaine
**with lidocaine

Predictable results

thanks to highest quality and safety

The unique combination of high molecular weight hyaluronic acid of non-animal origin, a reliable production process in expert hands to crosslink the hyaluronic acid chains and a thorough purification process result in the exceptional safety profile of Croma FILLER.

Croma - the experts in hyaluronic acid

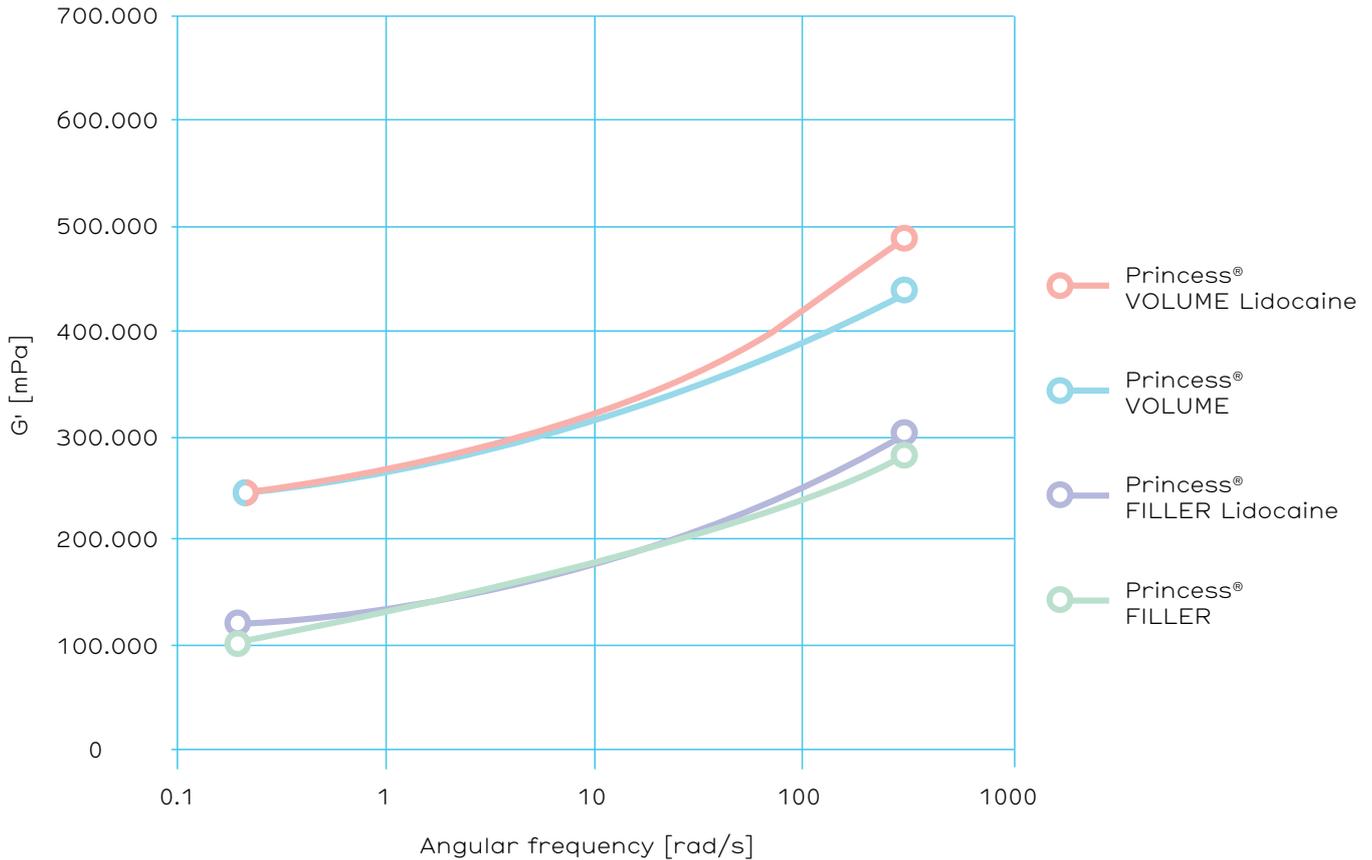
Croma has been manufacturing hyaluronic acid products for decades. As experts in HA with state-of-the-art facilities we pride ourselves on the high safety profile of our products. A glass syringe, low concentration of BDDE, stringent safety requirements and the overall performance of our Croma HA fillers are the reasons why doctors choose our aesthetic products.



MORE THAN
50
MILLION
SYRINGES
MANUFACTURED

G Prime [G']⁶

G' is a rheological parameter which indicates the stiffness of HA gels. A high G' represents the volumising capabilities of HA gels.

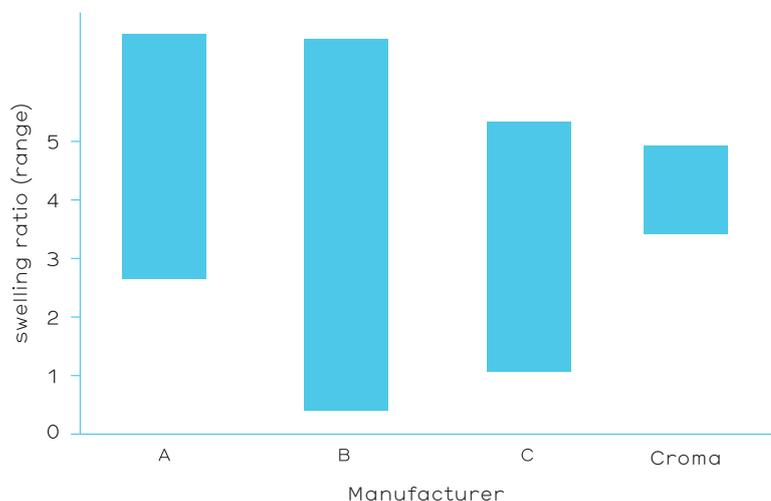


Swelling Ratio

Water uptake influences the volumising effect of HA fillers. Therefore, the in vitro swelling behaviour is a useful parameter. Cromia HA fillers show a reproducible swelling in vitro within the entire product range (compared to the competitor product ranges A, B, C in the table). Furthermore, Cromia HA fillers have a very low batch to batch variability, which contributes to the predictability of the results.

Test method

gravimetric measurement to determine the ability of a gel to take-up PBS (phosphate buffered saline)

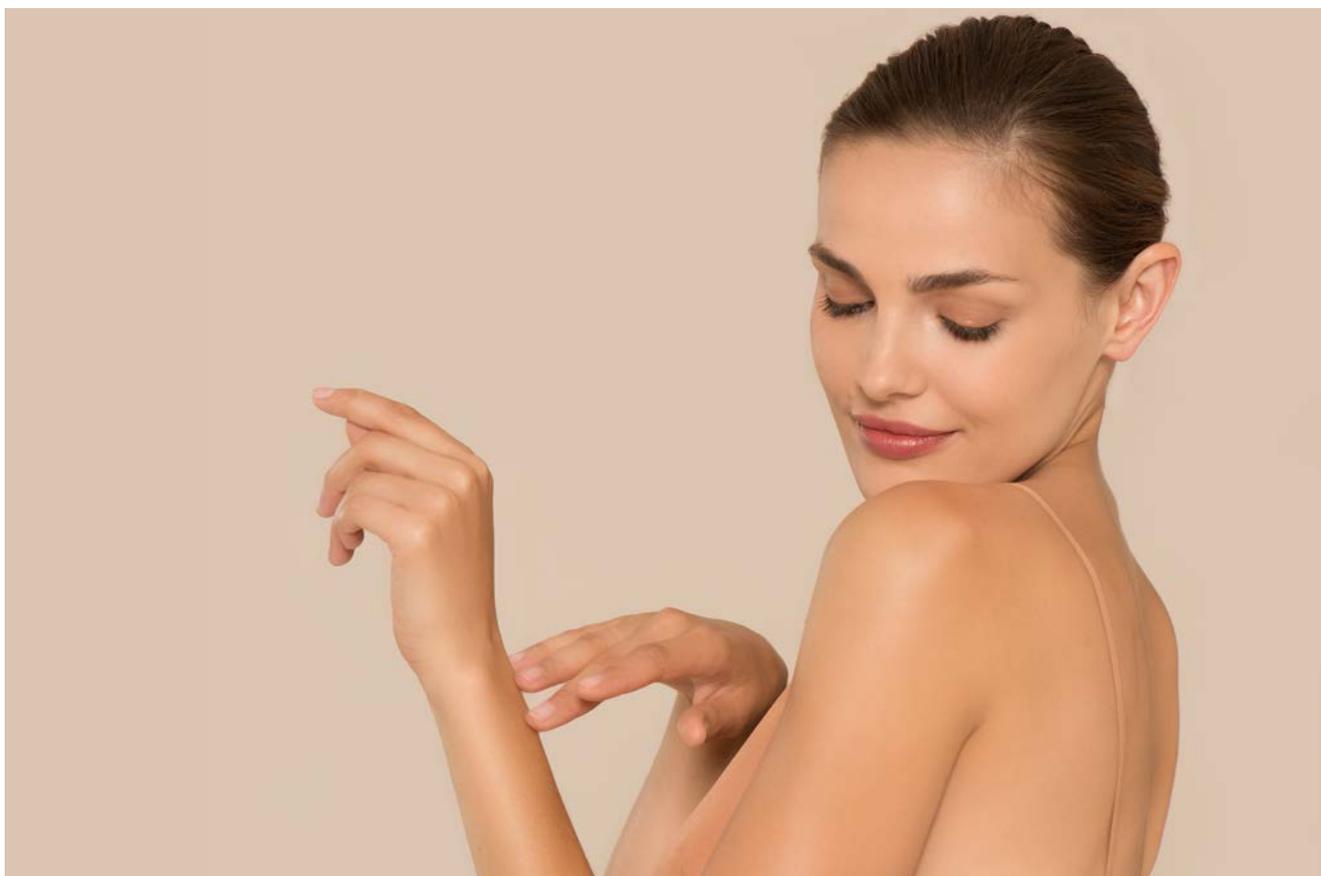


Cromia data on file

What makes Croma RICH so special?

Its particular combination of substances: hyaluronic acid and glycerol

Water in the epidermis and in the stratum corneum plays an important role in keeping the skin surface soft and smooth. Hyaluronic acid and glycerol protect the skin from drying out and keep the collagen fibres elastic. The more glycerol and hyaluronic acid are contained in the skin, the better its hydration – and hence the better it is protected from premature signs of aging. Unfortunately, the formation of hyaluronic acid and glycerol reduces with age.



Croma RICH is intended to replenish the loss of hyaluronic acid due to ageing, to improve hydration, tone and elasticity of the skin.

Croma RICH contains one of the highest HA concentrations (18 mg/ml) of all the non-crosslinked skin rejuvenation HA products on the market. The native hyaluronic acid used has an extraordinarily high molecular weight of over 3 million daltons.

Croma RICH

at a glance

Concentration HA	1.8% (18mg/ml)
Stabilizing agent	Glycerol 2.0% (20mg/ml)
Other ingredients	Phosphate citrate buffer
Needle	2 x 30 G 1/2" thin wall Terumo™ needles (CE 0197)
Packaging	Box of 1 ml syringe
Injection area	Superficial dermal tissue
Indication	Viscoelastic solution to replenish the loss of hyaluronic acid due to aging, , to improve the hydration, tone and elasticity of the skin.
Recommended treatment protocol	3 sessions at intervals of 2-3 weeks, then as required

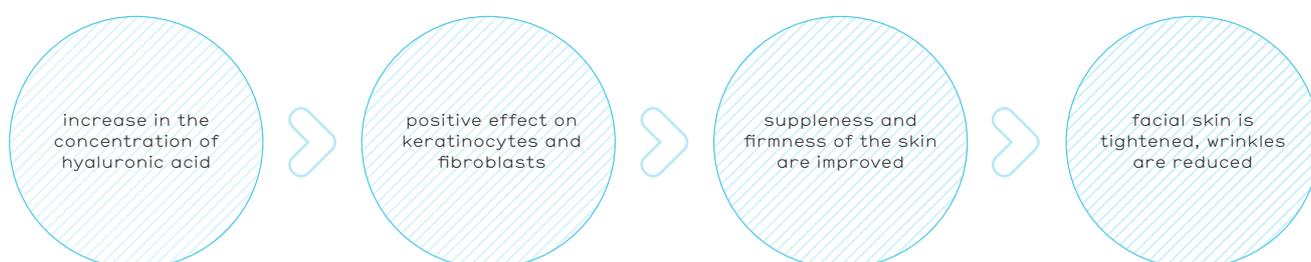
What is Croma RICH used for?

Croma RICH is a medical device based on native hyaluronic acid and glycerol, used for the rejuvenation of the skin and the prevention of signs of aging.

Treatments with Croma RICH help

- to provide the skin with an optimum supply of moisture, thus alleviating visible dryness and lack of elasticity
- to restore lost radiance and vitality to tired, jaded skin
- to improve the skin's hydration, tone and elasticity
- to create a fresher, healthier complexion

The skin's moisture content is important for wellbeing and beauty¹:



Hyaluronic acid – the be all and end all of skin rejuvenation

Hyaluronic acid is a glycosaminoglycan, a naturally occurring substance that is an important component of the human body. Due to its extraordinary ability to bind extremely large quantities of water (up to one thousand times its own weight), it is involved in maintaining the water balance in the body. The proportion of HA in connective tissue and the extracellular matrix is a determining factor in tissue tension and the shape of the organs and the body. An application of hyaluronic acid counteracts the thinning of the skin (about 0.6% per year) and age-related skin atrophy, and it has a positive effect on the skin's appearance.

Smooth filling enhancement with Croma FILLER



Nasolabial folds

Croma FILLER

Crosslinked hyaluronic acid

Concentration HA	2.3% (23 mg/ml)
Crosslinking agent	BDDE
Other ingredients	Phosphate buffer, NaCl
Needle	2 x 27G 1/2" thin wall Terumo™ needles (CE 0197)
Packaging	Box of 1 ml syringe
Injection area	Mid to deep dermis
Indication	For correcting moderate to severe nasolabial folds. Used for cosmetic and medical reconstructive purposes in the treatment of e.g. facial lipotrophy, debilitating scars or morphological asymmetry.
Estimated duration in the skin	Anticipated to be 6 to 9 months ⁵

Smooth filling enhancement with Croma FILLER Lidocaine



Croma FILLER Lidocaine

Crosslinked hyaluronic acid with 0.3% lidocaine

Concentration HA	2.3% (23mg/ml)
Crosslinking agent	BDDE
Other ingredients	Phosphate buffer, NaCl, 0.3% lidocaine hydrochloride
Needle	2 x 27G 1/2" thin wall Terumo™ needles (CE 0197)
Packaging	Box of 1 ml syringe
Injection area	Mid to deep dermis
Indication	to correct moderate to severe facial wrinkles and folds and to increase lip volume, for reconstructive treatment, for instance, of facial lipoatrophy, debilitating scars, or morphological asymmetry
Estimated duration in the skin	Up to 9 months ⁵

Optimal restoration of facial volume

with Croma **VOLUME**



Nasolabial folds

Croma **VOLUME**

Crosslinked hyaluronic acid

Concentration HA	2.3% (23 mg/ml)
Crosslinking agent	BDDE
Other ingredients	Phosphate buffer, NaCl
Needle	2 × 27G 1/2" thin wall Terumo™ needles (CE 0197)
Packaging	Box of 1 ml syringe
Injection area	Deep dermis or subcutis
Indication	For correcting moderate to severe nasolabial folds and medical reconstructive treatment, for instance, of facial lipoatrophy, debilitating scars, or morphological asymmetry
Estimated duration in the skin	At least 9 months ⁵

Optimal restoration of facial volume

with Croma **VOLUME Lidocaine**



Croma **VOLUME Lidocaine**

Crosslinked hyaluronic acid with 0.3% lidocaine

Concentration HA	2.3% (23 mg/ml)
Crosslinking agent	BDDE
Other ingredients	Phosphate buffer, NaCl, 0.3% lidocaine hydrochloride
Needle	2 x 27G ½" thin wall Terumo™ needles (CE 0197)
Packaging	Box of 1 ml syringe
Injection area	Deep dermis or subcutis
Indication	To correct deeper wrinkles and folds, increase or restore volume to the face and to remodel facial contours. The device is conceived for reconstructive treatment, for instance, of facial lipoatrophy, debilitating scars, or morphological asymmetry
Estimated duration in the skin	At least 9 months ⁵

The Croma HA filler product range

	replenish	smooth / fill	volumise
Product	<p>Croma RICH</p>  <p>CE 0459 Made in Austria</p>	<p>Croma FILLER with/without lidocaine</p>  <p>CE 0120 LIDOCAINE CE 0459 Made in Austria</p>	<p>Croma VOLUME with/without lidocaine</p>  <p>CE 0120 LIDOCAINE CE 0459 Made in Austria</p>
HA concentration	18mg/mL + Glycerol	23mg/mL Lidocaine: 0.3%	23mg/mL Lidocaine: 0.3%
Level of crosslinking	<p>○○○○</p> <p>non-crosslinked</p>	<p>●●○○</p>	<p>●●●○</p>
Mixing ratio crosslinked:non-crosslinked	–	91:9	95:5
Needles	2x30G 1/2" thin wall Terumo™ (CE 0197)	2x27G 1/2" thin wall Terumo™ (CE 0197)	2x27G 1/2" thin wall Terumo™ (CE 0197)
Packaging	1 mL glass syringe	1 mL glass syringe	1 mL glass syringe
Depth of injection	superficial dermal tissue	mid to deep dermis	deep dermis or subcutis

The medical practitioner confirms having informed the patient of a likely risk associated with the use of the medical device in line with its intended use. For risks and adverse events associated with the use of the product consult the instructions of use.

Croma portfolio

Without lidocaine



With lidocaine



HA: 18mg/ml+Glycerol
Level of crosslinking:
○○○○

HA: 23mg/ml
Level of crosslinking:
●●○○

HA: 23mg/ml
Level of crosslinking:
●●●○

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Croma Pharma



cromapharma_international

Sources:

¹ Croma's medical advisory board consisted of eight experienced specialists from eight different countries. ² Evaluation of component stability in accordance with ASTM D4169 and material qualification of components. ³ Post Market Surveillance outcome and specification for needles. ⁴ EPC (End Product Control): Extrusion force is tested on every batch. ⁵ Arruda LHF, Costa A, Pereira ESP, de Oliveira Pereira M, Assumpção EC (2013) Evaluation of Clinical Safety and Effectiveness of Hyaluronic Acid-based Temporary Dermal Filler Used in Nasolabial Folds. J Clin Exp Dermatol Res 4: 196. doi:10.4172/2155-9554.1000196, Kopera, D., Ivezic-Schoenfeld, Z., Federspiel, I. G., Grablowitz, D., Gehl, B., & Prinz, M. (2018). Treatment of facial lipoatrophy, morphological asymmetry, or debilitating scars with the hyaluronic acid dermal filler Princess® FILLER. Clinical, cosmetic and investigational dermatology, 11, 621-628. doi:10.2147/CCID.S181964, Princess® FILLER was previously known as Princess® FILLER, ⁶ Data on file.

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