

### **A new generation of cross-linked hyaluronic acid fillers**

HYAMIRA is a sterile, highly tolerated, viscoelastic filler made with cross-linked hyaluronic acid, ideal for subcutaneous applications.

HYAMIRA helps to increase the volume of the dermo-epidermal tissue thanks to the natural ability of hydrophilic hyaluronic acid molecules to attract a moderate amount of water molecules and bond with them.

This allows the integration of the intercellular matrix, whilst filling intradermal spaces and making the tissues firmer. The cross-linked hyaluronic acid contained in the product makes this filling effect longer lasting and more stable. In fact, unlike linear hyaluronic acid, the skin slowly absorbs HYAMIRA in 6 to 8 months, looking more natural for longer. In addition to safety, BDDE – the cross-linking agent – provides effective results, thereby meeting market requirements.

HYAMIRA is an injectable, apyrogenic, resorbable medical device made with cross-linked hyaluronic acid created from non-animal sourced bacterial bio-fermentation.

It is a colourless monophasic gel contained in a disposable pre-filled, ergonomic syringe with a Luer Lock adapter.

The syringe is equipped with a plastic support that makes it easy to handle. Its accurate graduation allows you to control and read the volume of injected product.

Electronic verifications carried out throughout the entire filler production and packaging process, based on the use of state of the art technology, ensure quality, purity, and safety.

These production standards, together with the extremely low concentration of nucleic acids and protein, and the bacterial endotoxin rate  $< 0.5$  EU/ml (much lower than the limit established by the European Pharmacopoeia for injectable products) minimise any hypersensitivity reaction.

## **RESULTS**

Three different dosages allow for the treatment of any area of the face, reducing any type of wrinkle (fine to deep), reshaping the face contour and lips, and hydrating the skin in depth. The result is very natural and immediately visible. HYAMIRA has an immediate lifting effect, thanks to its intrinsic viscoelastic and hydrophilic properties, which help recreate the desired volume.

HYAMIRA is injected subcutaneously to eliminate or at least reduce both superficial and deep wrinkles and increase soft tissue volume (lips, cheekbones, cheeks) for face countouring or reconstructive procedures (depressed scars, acne or chicken pox outcomes, facial asymmetry and atrophy, non-surgical rhinoplasty). This allows for safe, long-lasting results, considering that resorption occurs gradually over 6 to 8 months from treatment. The treatment can be safely repeated once the filling effects are significantly attenuated.

Ease of use and intrinsic safety facilitate the physician performing the treatment. After thorough cleansing and disinfection of the skin, a few microinjections in the areas to be treated is all it takes. The treatment is well tolerated and not painful.

## **HYAMIRA SOFT**

- Treatment of periorcular wrinkles

We recommend the linear retrograde injection technique, which should trace the path of the wrinkle with extreme precision. Avoid hypercorrections. This technique requires stretching the skin between the fingers of the hand not holding the syringe, carefully avoiding surface capillaries. After the injection, it is important to massage the treated area to spread the product subcutaneously.

## **HYAMIRA BASIC**

- Treatment of perioral wrinkles and for lip and eyebrow contouring.

The product is injected into the superficial dermis, avoiding hypercorrections. If necessary, the physician can perform corrections with both the serial puncture and linear retrograde techniques, according to her dexterity. We recommend massaging the treated parts.

## **HYAMIRA FORTE**

- Treatment of medium to deep face wrinkles, volume augmentation of cheekbones, chin, nose bridge and lips.

The linear retrograde technique should be chosen over the serial puncture technique. We recommend injecting the product into the deep dermal layer.

Technical data

	<b>HYAMIRA SOFT</b>	<b>HYAMIRA BASIC</b>	<b>HYAMIRA FORTE</b>
Main ingredient	Reticulated hyaluronic acid	Reticulated hyaluronic acid	Reticulated hyaluronic acid
Source	Bacterial fermentation	Bacterial fermentation	Bacterial fermentation
Concentration	15 mg/ml	20 mg/ml	25 mg/ml
pH	6.00 – 7.50	6.00 – 7.50	6.00 – 7.50
Initial hyaluronic acid molecular weight	2,400-4,000 kDa	2,400-4,000 kDa	2,400-4,000 kDa
Cross-linking agent	BDDE < 0.5 ppb	BDDE < 0.5 ppb	BDDE < 0.5 ppb
Total endotoxins	< 0.5 EU/ml	< 0.5 EU/ml	< 0.5 EU/ml
Sterilization	Autoclave	Autoclave	Autoclave
Indications	Treatment of periocular wrinkles	Treatment of perioral wrinkles and for lip and eyebrow contouring	Treatment of deep facial wrinkles, volume augmentation of cheekbones, chin, nose bridge and lips
Injection area	Medium-deep dermal layer, labial submucosa	Possibly the deepest dermal layer	Deep or supraperiosteal hypodermis
Duration of results	4-5 months	5-7 months	7-9 months
Needles	30 G 1/2"	27G 1/2" or 26G 1/2"	27G 1/2" or 26G 1/2"



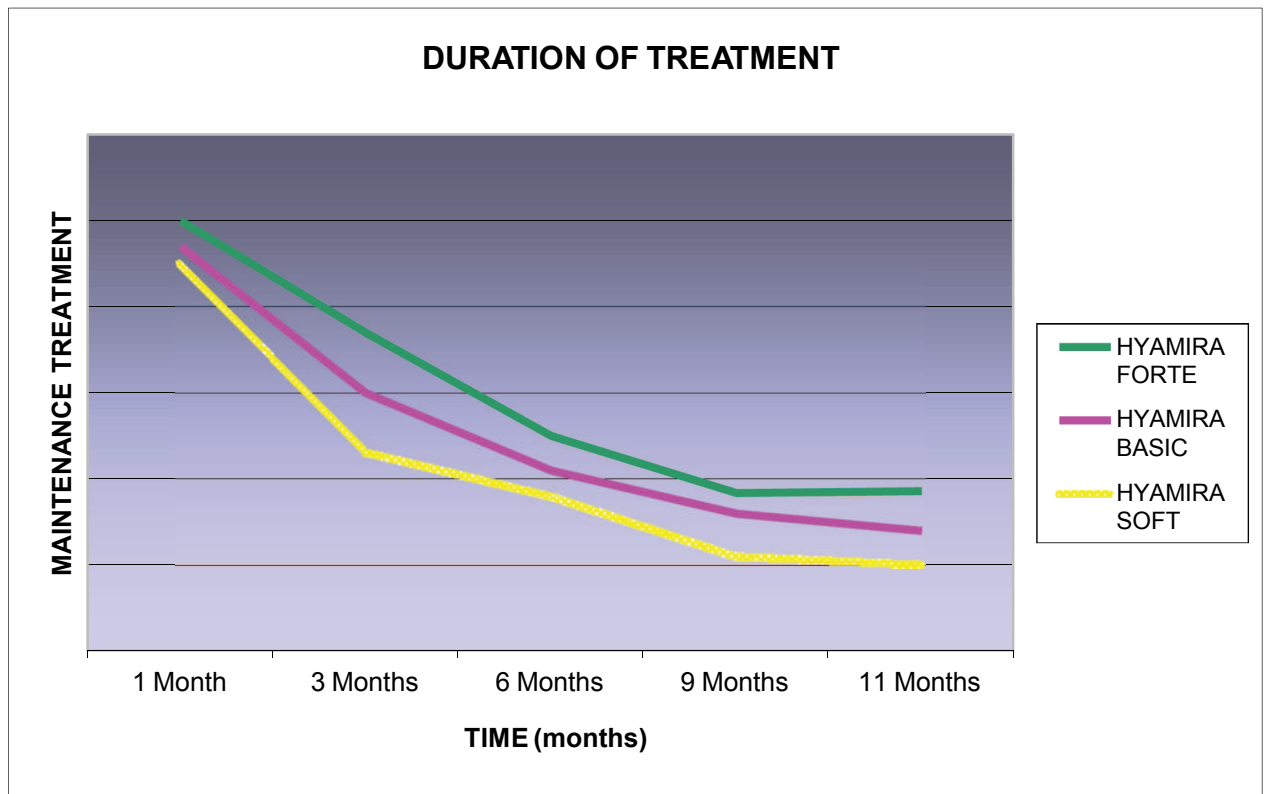
Medical device **CE**<sub>0373</sub>

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## CLINICAL TRIALS

A preclinical trial conducted by ten specialists (dermatologists, plastic surgeons, and cosmetic physicians) on 145 patients (women with a mean age of 50 years) over the course of one year has shown an excellent durability of the product.

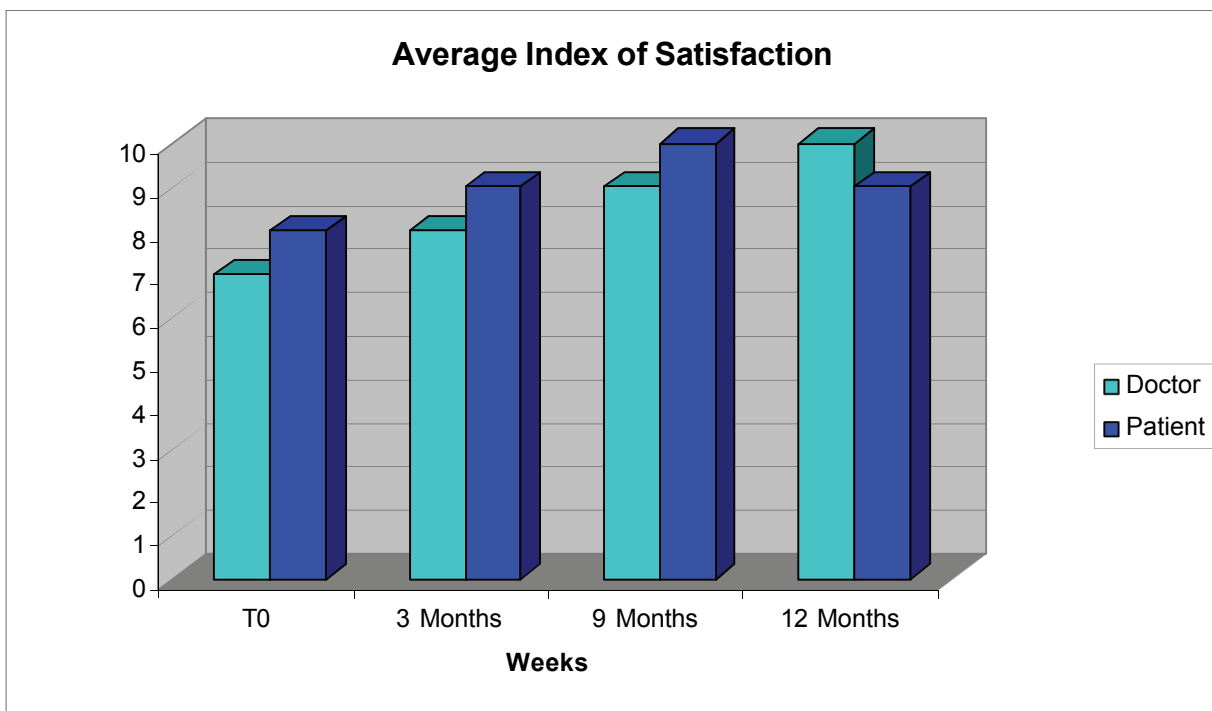
The graph below shows the duration of the treatment with the three dosages.



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The satisfaction questionnaires filled out by the specialists involved in the study showed an average satisfaction index (ASI) of 8/10 for both patients and physicians.

The parameters taken into the consideration in the questionnaire were the malleability and tolerability of the product, its immediate effect, pain during the treatment (which resulted to be non-existent or tolerable) and the absence of oedema.



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