Natinuel
MEDICAL DEVICE

Alium | h24 | h28

NATURAL AESTHETIC EFFECT

- safety
- ease of use
- durability

Alium h24 / Alium h28

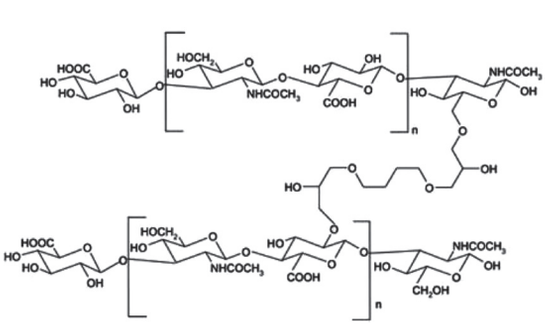
Next-generation filler

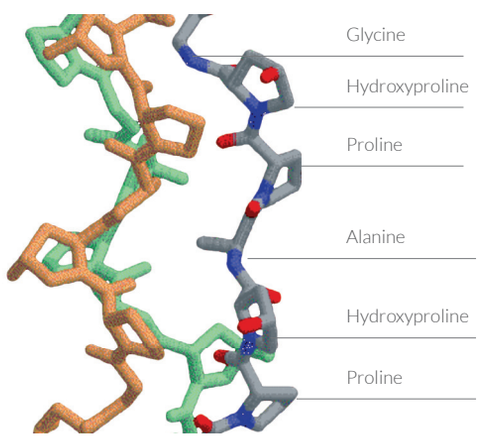
Medical products falling within Class III, intended for correcting congenital and acquired soft tissue deficits. Available in mono-phase sterile hydrogel form, intended for injection, non-pyrogenic, consisting of **sodium hyaluronate cross-linked via the 1,4-butanediol-diglycidylether (BDDE) cross-linking agent, containing two amino acids (glycine and L-proline)**, buffered with non-pyrogenic water. The products have a pH of 6.5 ± 1, they have very good mechanical properties such as viscosity and flexibility and high compression strength and cohesion in the presence of water.

The product is resorbed within 8/12 months after injection.

No raw materials of animal origin were used for the production of ALIUM.

Cross-linking using BDDE





Glycine and L-proline increase collagen synthesis in human fibroblast cells (Karna et al.2001).

Alium h24 / Alium h28

Reliable and permanent filler

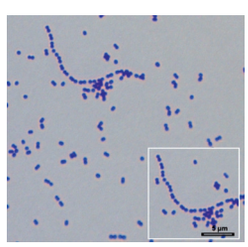
Sodium hyaluronate, used in **Alium h24 and Alium h28**, is raw material purified by bacterial fermentation (biotechnological method) using Streptococcus Equi. It is a naturally occurring strain of bacteria, not a genetically modified organism. This strain of bacteria ensures highest purity and safety as it does not produce streptokinase, hyaluronidase, erythrogenic toxins, hemolysin, endotoxin or any other toxins or immunogenic contaminants.

Alium h24-h28 hydrogel has the following chemical and physical properties:

Appearance:
transparent and colourless

Solid: 3.5 ± 1.5 %	
pH: 6.5 ± 1.0	Non - toxic
BDDE residue <2ppm	Non - sensitizing
Sterility: Sterile	Non - mutagenic
Endotoxins: <0.5 EU/ml	Biodegradable

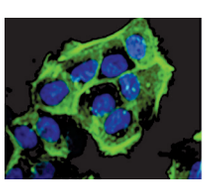
Lack of enzyme (hyaluronidase) activity accounts for the potential of a particular strain to produce hyaluronic acid of high molecular weight.



Streptococcus Equi

Sodium hyaluronate

SAFETY TESTS



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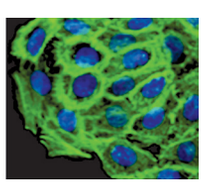
Damage



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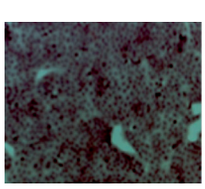

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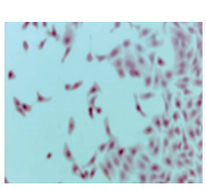

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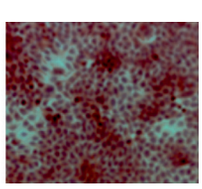

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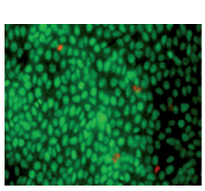

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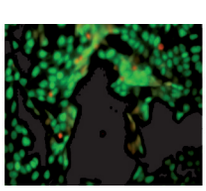

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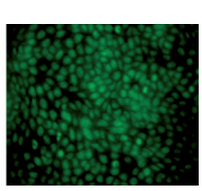


Product

The first test:
the product does not induce damage of cell structures

The second test:
the product has no effect on cell morphology

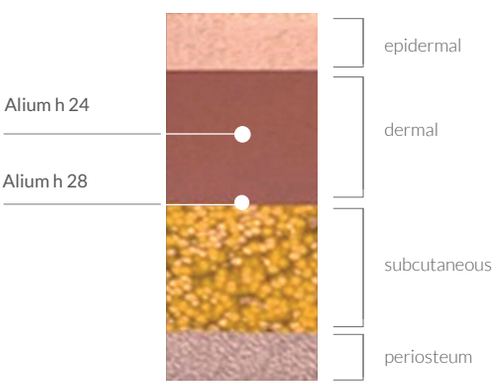
The third test:
the product has no effect on cell viability

Alium h24

The product with a concentration of 24 mg/ml of hyaluronic acid is injected into the middle dermis and it is perfect for the correction of nasolabial folds, surface wrinkles, lacrimal grooves and the wrinkles in the under-eye area. The product is perfect for increasing lip volume and shaping the area of the mouth.

Alium h28

The product with a concentration of 28 mg/ml of hyaluronic acid is injected into the deep dermis and it is perfect for the correction of deep wrinkles, shaping the area of zygomatic bones, the cheeks, jawline, chin creases and for nose correction. The product is perfect for improving face contour.

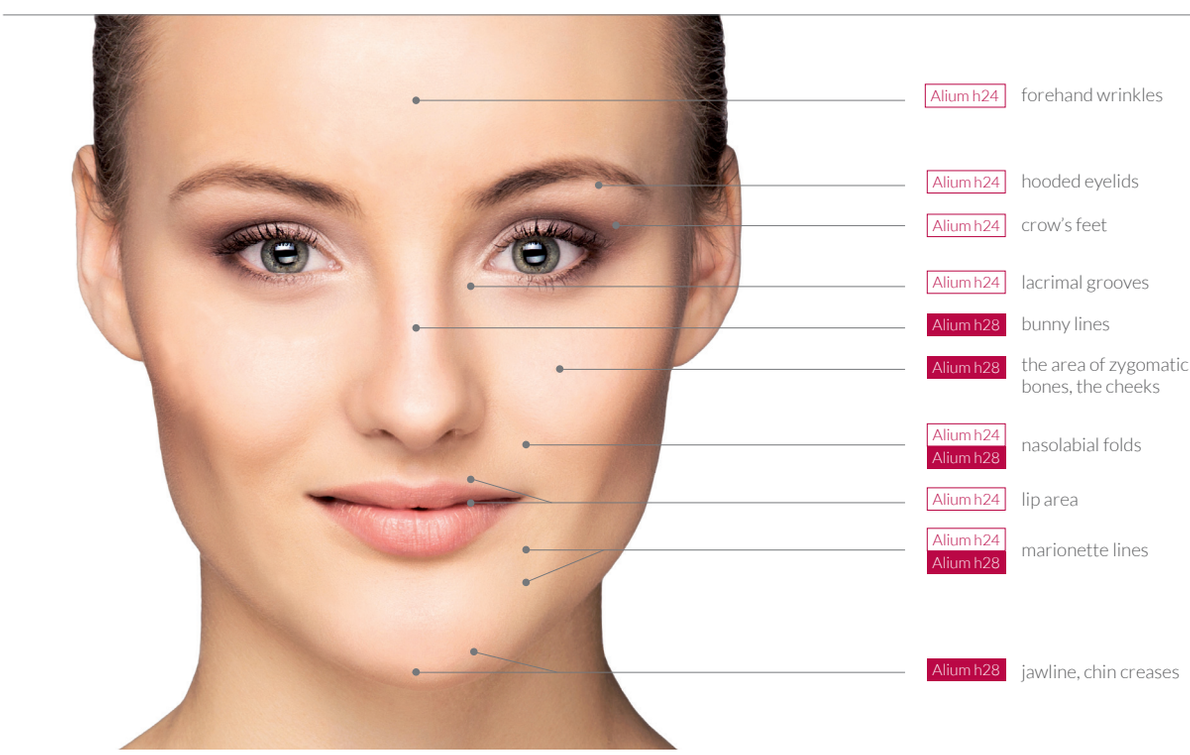


Summary of product characteristics

The main purpose of the summary of characteristics of Alium h24 Alium h28 based on hyaluronic acid cross-linked via BDDE is to find optimum conditions for injecting the hydrogel into the skin using a syringe, without changing its structure. The optimal solution is obtained by combining needle diameter and the size of the syringe with viscoelastic properties of the product. The results show that **Alium h24** should be injected using needle 27G (TSK), whereas **Alium h28** should be injected using needle 25G (TSK).

RANGE OF EXTRUSION FORCE {N}

	NEEDLE	RANGE {N}
24 mg/ml	27G	18-28
28 mg/ml	25G	15-25



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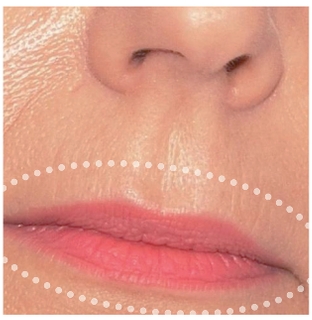

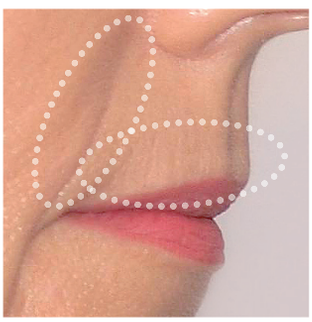

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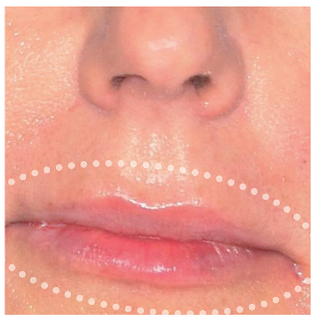
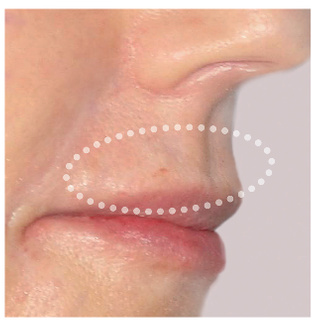
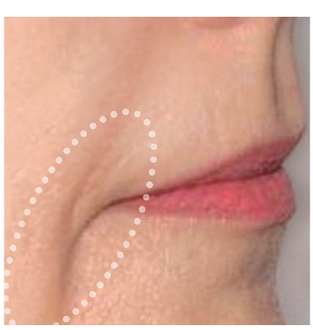




Alium h24

- average concentration of hyaluronic acid, high flexibility
- natural effect and increased patient comfort
- high standard of safety
- slow biodegradation and long-lasting effect

BEFORE



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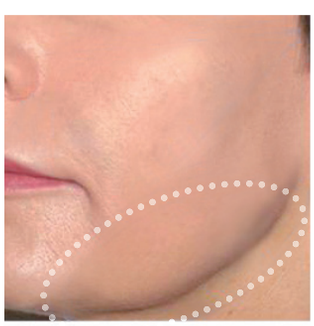

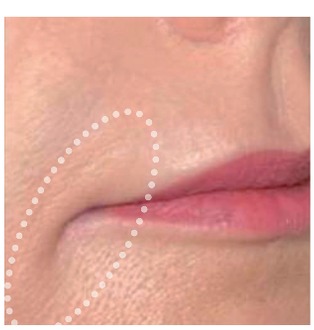

Alium h28

- high concentration of hyaluronic acid, high flexibility
- optimum rheological properties ensuring natural effect
- high standard of safety
- slow biodegradation and long-lasting effect

COMIDERMA
dermocosmetic research

Contrada San Giovanni 63074 S. Benedetto T. (AP) - ITALY
tel./fax +39 0735 762250 / tel. cell: +39 331 4255663