croma

Princess® RICH

Technical factsheet

Princess® RICH[1]	
Indication	to replenish the loss of hyaluronic acid due to aging, to improve hydration, tone and elasticity of the skin
Injection area	superficial dermal tissue
Ingredients	
Concentration HA	1.8 % (18 mg/mL) high molecular weight hyaluronic acid of non-animal origin
Additional ingredients	glycerol (20 mg/mL) glycerol is a polyalcohol with the double role of stabilizing hyaluronic acid and promoting skin hydration[2]
Buffer system	phosphate citrate buffer
Packaging	
Packaging unit	1 box of 1 mL syringe
Needle	2 x 30G ½" thin wall Terumo™ needles (CE 0197)

Rheology

Purpose of rheological measurements is to evaluate the physical characteristics of dermal fillers. The dynamic viscosity represents a suitable parameter to determine the viscous properties of HA-based, non-crosslinked products like Princess® RICH, where the viscosity is more pronounced than the elasticity.

Test method dynamic viscosity ($D=5s^{-1}$, T=25°C)
Result 30,104 mPa.s[3]

Extrusion force

Extrusion force measurements are conducted to determine the force [N] needed to eject the gel from the syringe. The tests are always performed with the enclosed needle. A low and constant extrusion force is beneficial for smooth and predictable results.

Needle 30G ½" thin wall Terumo™ (CE 0197)
Result 8N[4]

Microbiological parameters

Endotoxins

Endotoxins are components of gram-negative bacteria membranes and are released when the bacterial cells are disrupted (e.g. during sterilisation). Therefore the products are tested to assure that the endotoxin concentration lies below the predefined specification limits.

Test method according to Ph.Eur.[5]
Result virtually free on endotoxins[6]

Sterility

Croma HA fillers are steam sterilised within the syringe.

[1] CE 0459, [2] Fluhr et al, Glycerol and the skin: holistic approach to its origin and functions, 2008, British Journal of Dermatology 2008 159, pp 23-34, [3] Batch: 403051, specification limits: > 20,000 mPa.s, [4] Batch: 403054, specification limits: ≤ 12N, [5] Ph.Eur. = European Pharmacopoeia, [6] EU = Endotoxin Unit according to Ph.Eur., specification limits: < 0.5 EU/mL

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.

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