

# HyalOne



Hyaluronic acid sodium salt  
1.5% solution (60 mg/4ml)

## Product rationale

Hyaluronic acid (HA) is a major component of the articular tissues, where it is thought to be essential in the protection of articular cartilage and the transport of nutrients to cartilage (*Punzi L, 2001*).

The high concentration of HA in synovial fluid (SF) is crucial for normal joint function, since it confers SF its exceptional viscoelastic and lubricating properties, particularly during high shear conditions. The rheological properties of HA not only reduce cartilage wear and attrition during joint motion, but also stabilize joints at low shear rates (*Guidolin D, 2014*).

In traumatic and degenerative joint disorders, an insufficient amount of hyaluronic acid and a loss of viscosity occur in synovial fluid, resulting in impaired joint function and painful symptoms. Extensive literature data indicate that intra-articular administration of hyaluronic acid is capable of restoring the viscoelastic properties of the synovial fluid, thereby alleviating pain and improving joint mobility (*HyalOne Prescribing Information*).

*HyalOne is a sterile, non pyrogenic, viscoelastic solution containing **Hyaluronic Acid sodium salt 1.5%**, obtained by bacterial fermentation from a fraction of high molecular weight.*

**Principal Ingredient:**

Hyaluronic acid sodium salt 1.5% solution (60 mg/4 mL)

**Indications:**

HyalOne is a temporary synovial fluid replacement for patients affected by degenerative or mechanical arthropathy of the hip and knee, that causes an alteration of the functional performance of the synovial fluid, without active synovitis

**Presentation:** 1 Pre-filled syringe (60 mg/4 mL)

**Classification:** Medical device (Class III) - CE 0459

**Regimen:**

Mono injection. When HyalOne is used in the **HIP**, it is recommended to perform the injection under ultra-sound guidance. Further treatment after the first application may be needed to maintain the benefit of the treatment over time, depending on the individual patient need. Product administration should be performed exclusively by qualified physicians.

## Clinical evidence

**Vetro A et al., 2014**

The present study shows that a single intra-articular injection of HyalOne in 168 patients suffering from **knee OA** is well tolerated and provides pain relief up to 6 months at least. Benefit to knee function was confirmed by both the WOMAC and the KOOS scores.

**Migliore A et al., 2012**

HyalOne, given by ultrasound-guided injection (1 shot every 6 months), shows to delay THR in 82% of **hip OA** patients candidate for surgery up to 4 years. In actual clinical practice, hip viscosupplementation should be considered as a conservative treatment to perform before surgery.

**Migliore A et al., 2017**

The data of this study in real life (1,022 patients - under 40, up to over 80 years), extended **up to 7 years**, confirm the **efficacy and safety** of the intra-articular treatment with HyalOne at 4 mL dose (1 shot every 6 months) in **symptomatic hip OA** patients.

## HyalOne Key Features

- **Natural, high molecular weight hyaluronic acid** (*Summary of Product Characteristics*)
- **"One-shot" administration** (*Migliore A, 2011*)
- **Clinical evidence up to 7 years** (*Migliore A, 2017*)
- **Optimal tolerability** (*Guidolin D, 2014*)
- **Efficacy and safety data confirmed in real practice** (*Migliore A, 2011; Migliore A, 2017*)