DUROLANE is a single injection treatment to relieve OA joint pain. It is based upon a safe and proven technology of non-animal stabilized hyaluronic acid, NASHA. DUROLANE contains 20 mg/mL of stabilized, NASHA in buffered physiological sodium chloride solution pH 7.2.

### Summary of Indications for Use

**DUROLANE (3 mL):**
- Symptomatic treatment of mild to moderate knee or hip osteoarthritis. In addition, DUROLANE has been approved in Canada for the symptomatic treatment associated with mild to moderate osteoarthritis in the ankle, elbow, wrist, fingers, and toes.
- DUROLANE SJ (1 mL):
  - Symptomatic treatment of mild to moderate knee osteoarthritis.
  - It is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within 3 months of the procedure.

### References:


### DUROLANE.com

BioventusGlobal.com

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DUROLANE advanced and unique NASHA® technology

**DUROLANE** is a stabilized hyaluronic acid (HA) therapy, from a non-animal source, for the intraarticular treatment of mild to moderate OA.

**DUROLANE** uses advanced and unique NASHA technology which gives it a unique gel bead structure. The patented stabilization technique ensures that the naturally cross-linked and entangled HA network is kept in place by introducing a very limited number of synthetic cross-links, resulting in minimal modification.

**NASHA structure**

Entanglement of HA chains (natural cross-links)

Covalent bond (<1% modification)

Stabilized HA: 1% stabilization forms a flexible molecular network which resists physiological catabolism.

**For intraarticular needle placement in knees with no effusion, an accuracy rate of 93% has been reported using a lateral midpatellar extended-leg injection approach.**

A history of safe use

**DUROLANE** does not generate product-specific antibodies

Mice were injected with different HA products under the skin in an air pouch. Then blood samples were obtained to test for antibody production.

- Antibody levels in blood taken from DUROLANE-treated animals were no different than controls.
- DUROLANE did not cause a systemic immune response.
- Antibody levels in blood taken from hylan G-F 20 treated animals were greater than in blood taken from animals treated with **DUROLANE**.
- Hylan G-F 20 stimulated a systemic immune response.

Significant and sustained benefits for OA patients

**Effectiveness in comparison to corticosteroid**

A randomized, blinded trial comparing DUROLANE to methylprednisolone acetate (MPA) for knee OA pain.

- Longer lasting at 26 weeks—DUROLANE showed a significant improvement from baseline in **Osteoarthritis Research Society International** (OARSI) pain score compared to MPA at week 26 (p<0.001), using the prespecified repeated measures model.
- Patients who received a second injection of DUROLANE at 26 weeks showed higher OARSI pain responder rates at 26 and 52 weeks than at 26 weeks.

**Pain responder rate** was defined as an improvement in WOMAC pain score of at least 40% vs baseline and an absolute improvement of at least five points.

**Pre-clinical evidence for the efficacy of DUROLANE**

**DUROLANE** prevented knee OA progression in an animal model

**DUROLANE** provided superior pain relief, compared to 750 kDa HA and hylan G-F 20, in an animal knee joint pain model.

Long lasting by design

**DUROLANE** uses unique and advanced NASHA technology to increase residence time in the joint

Data from human and animal studies have shown that:

- **DUROLANE** has a half-life of 4 weeks in the knee joint following a single treatment injection regimen.
- **DUROLANE** has a longer half-life than unmodified HA and cross-linked Synvisc (hylan G-F 20).

**DUROLANE** has a longer half-life than methylprednisolone acetate (MPA) at week 26 (p<0.001) and unmodified sodium hyaluronate, particularly in the later stages.

In vitro and in vivo performance may not be predictive of performance in humans.

Note:

- The clinical relevance of this information has not been determined.

**Preclinical dose selected: NASHA (DUROLANE), hylan G-F 20 (Synvisc®) and unmodified sodium hyaluronate (Hyalgan®).**

**NOTE:** Clinical dosage of Hyalgan® is three or five injections. Model utilized single injection.