

DUROLANE[®]

hyaluronic acid, stabilized single injection

 **bioventus**[®]

A safe¹ and effective
treatment for joints of all sizes⁶

Relieve painful
osteoarthritis with a
single-injection treatment

DUROLANE

The original single injection

since 2001



DUROLANE is the original single injection designed to relieve painful osteoarthritis (OA) in the knee or hip joint.⁶ If you have any further questions after reading this brochure you should talk to your doctor.

What is OA?

OA is often referred to as 'degenerative joint disease' and usually develops slowly, over a period of years. It is a very common disease — 6% of adults aged 30 and above have frequent knee pain.² Over time, the cartilage on the surface of the joint starts to get damaged and wear away and this causes pain and stiffness in the joint.

What is hyaluronic acid (HA)?

HA is a molecule found naturally throughout the human body. It is an important component of the joint fluid (synovial fluid). The synovial fluid allows joints to move easily and freely while also absorbing the shock during activity. In a healthy joint, the joint fluid helps to protect bones and other joint tissues from injury and disease.

Why is HA important in OA?

The HA in your joint tissues is continuously broken down and replaced over time. During the slow progression of OA, the HA is broken down faster than it is replaced in the joint tissues. This has a negative effect on the properties of the joint fluid causing it to change and stop working properly.

What is DUROLANE?

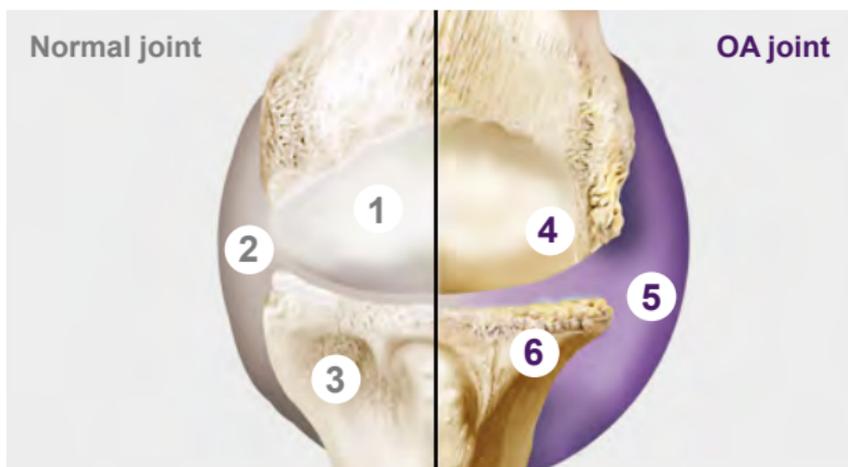
DUROLANE is the original single-injection treatment designed to relieve the pain in your OA joint. It may help bring back some of the life you remember — pain free and flexible.

How does DUROLANE work?

DUROLANE is a stabilised non-animal HA. It is the only HA product that uses advanced and unique NASHA[®] technology. This means that the HA is natural, safe and is highly concentrated. DUROLANE is made of the natural HA exactly as the HA in the joint fluid.



Inside an OA joint



- 1. Normal cartilage:** Provides a smooth surface allowing bones to move easily across each other
- 2. Synovial fluid:** Lubricates and provides shock absorption during activity due to a high concentration of HA
- 3. Normal bone:** Provides strength and support for the body's tissue
- 4. Eroded cartilage:** If completely worn away, bones may scrape painfully against each other
- 5. OA synovial fluid:** The osteoarthritis disease leads to a poor quality of HA production
- 6. OA bone:** Bony spur growth (osteophytes)

Why do you feel pain?

Bones: Start to grow bony spurs called 'osteophytes' that restrict movement and cause pain

Joint capsule: The tissue can become thick and swollen, and sometimes inflamed

Cartilage: As it becomes degraded, bones are shown to get closer together on X-Rays and movement becomes more difficult over time

Joint fluid: Joint fluid becomes degraded and less viable to perform its functions

How long does DUROLANE last?

DUROLANE effectively relieves pain and restores function for up to six months.^{3,4}



Is there any reason why I couldn't have a DUROLANE injection?

There are no known contraindications with DUROLANE. This means that in principle there are no restrictions to receive a DUROLANE injection to treat your OA pain. However the treatment that you receive will be decided between you and your doctor.

What treatment options are available? Is DUROLANE right for me?

You should talk to your doctor about the treatment options available for your specific circumstance. The more information you can give your doctor about how you feel and what you can (and can't) do, the more effective your OA treatment plan will be. When talking to your doctor, follow the tips below and try to make your descriptions as thorough as possible. It may help to write down some observations that you can bring to the appointment.

- Describe your OA joint pain in detail. Are there certain areas that hurt more than others? Does this happen at certain times of the day?
- Discuss the effects on your lifestyle. Do any specific activities cause you joint pain or discomfort, such as working, exercising, gardening, golfing etc?
- Tell your doctor about how you've adjusted your lifestyle to compensate for your joint pain and the results.
- Be sure to mention any medications or treatments you have used to relieve your OA joint pain. Did you notice any difference? Were there any side effects?





How do I know if I have OA?

Your doctor will diagnose you but you can help understand your pain better by filling out the self-assessment questions below.

	YES	NO
I frequently experience stiffness in my joints after resting or when I wake up	<input type="checkbox"/>	<input type="checkbox"/>
My joint is tender or sore after overuse	<input type="checkbox"/>	<input type="checkbox"/>
I feel pain in my joints when I move	<input type="checkbox"/>	<input type="checkbox"/>
I feel pain in my joints even when I am not active	<input type="checkbox"/>	<input type="checkbox"/>
Getting up from a chair, out of a car, or going up or down stairs is difficult	<input type="checkbox"/>	<input type="checkbox"/>
I hear a crackling sound in my joints when I move	<input type="checkbox"/>	<input type="checkbox"/>
I experience a grating feeling in my joints when I move	<input type="checkbox"/>	<input type="checkbox"/>
The area around my joint is red and swollen	<input type="checkbox"/>	<input type="checkbox"/>
I am unable to do or enjoy certain activities because of pain or stiffness in my joints	<input type="checkbox"/>	<input type="checkbox"/>
I feel less coordinated due to pain or stiffness in my joints	<input type="checkbox"/>	<input type="checkbox"/>
I have noticed that the muscles close to my painful joint are not as strong as they used to be	<input type="checkbox"/>	<input type="checkbox"/>

If any of the above statements apply to you, you should see a doctor to get diagnosed. If OA is detected early – or at least earlier – then patients can get treatment sooner and treatment progress could be better monitored, potentially leading to better outcomes.⁵

What should I expect after a DUROLANE treatment?

Ask your doctor for post-injection advice — these represent general guidelines only:

- As with any invasive joint procedure, it is recommended to avoid strenuous activity (e.g. tennis, jogging or long walks) for the first two days after the injection.⁶
- During the first week following the injection, some transient reactions related to the injection may occur. Symptoms such as pain and/or swelling/stiffness of mild to moderate intensity can be anticipated. If the symptoms last for more than a week a doctor should be contacted.⁶



Summary of Indications for Use

DUROLANE (3ml): Symptomatic treatment of mild to moderate knee or hip osteoarthritis. In addition, DUROLANE has been approved in the EU for the symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, shoulder, elbow, wrist, fingers, and toes.

DUROLANE SJ (1ml): Symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, elbow, wrist, fingers, and toes.

Both DUROLANE and DUROLANE SJ are also indicated for pain following joint arthroscopy in the presence of osteoarthritis within 3 months of the procedure.

There are no known contraindications.

You should not use DUROLANE if you have infections or skin disease at the injection site. DUROLANE has not been tested in pregnant or lactating women, or children. Risks can include transient pain, swelling and/or stiffness at the injection site.

Full prescribing information can be found in product labeling, or at www.durolane.com.

Product codes:	DUROLANE (3ml)	1082010
	DUROLANE SJ (1ml)	1082004

References

1. RPT-000374 Data on File MA 12414 - Report of Prior Clinical Investigations DUROLANE.
2. Hunter DJ, Felson DT. Osteoarthritis. *BMJ*. 2006 18;332(7542): 639- 42.
3. Leighton R, Åkermark C, Therrien R, et. al. NASHA hyaluronic acid vs methylprednisolone for knee osteoarthritis: a prospective, multi-centre, randomized, non-inferiority trial. *Osteoarthritis & Cartilage*. 2014; 22(1):17-25.
4. McGrath A, McGrath AM, Jessop ZM, et al. A Comparison of Intra-Articular Hyaluronic Acid Competitors in the Treatment of Mild to Moderate Knee Osteoarthritis. *J Arthritis*. 2013; 2:1. doi.10.4172/2167-7921.1000108.
5. Early Detection for OA. Arthritis Foundation Web site. <http://www.arthritis.org/about-arthritis/types-of-arthritis/osteoarthritis/what-you-need-to-know/biochemical-markers.php>. Published 2015. Accessed January 28, 2015.
6. DUROLANE Product Insert: 3ML (Dec. 2013) and SJ 1ML (Dec. 2013).

To find out more about DUROLANE please visit our website:

www.durolane.com

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