

DUROLANE® INSTRUCTIONS FOR USE en

Contents
Each mL contains:
Hydrous corticosteroid stabilized 20 mg
Phys. sodium chloride solution, pH 7 u.s.
0.9% (equivalent to 2 ppm of 1,4-butanediol glycolyl) after (BDE) used to stabilize the gel.

Description
DUROLANE is an intra-articular injection for the symptomatic treatment of mild to moderate knee or hip osteoarthritis. In addition, DUROLANE is used for intra-articular injection for symptomatic treatment of mild to moderate osteoarthritis of indicated synovial joints, such as the ankle, shoulder, elbow, wrist, finger and toes. DUROLANE is also indicated for pain following joint arthroscopy in the presence of osteoarthritis with or without effusion. It should be injected by an authorized physician, or in accordance with the instructions for use.

DUROLANE contains 20 mg/mL of stabilized non-animal hyaluronic acid in buffered physiological sodium chloride solution pH 7. DUROLANE is a sterile, transparent viscous gel, packaged in a 3 mL glass syringe. The product is for single use only.

Hyaluronic acid is identical in all living organisms. It is a natural polysaccharide that is present throughout most of the body, with particularly high concentrations in the synovial fluid and the skin. DUROLANE is composed of biosynthetically produced hyaluronic acid that has been purified and stabilized. DUROLANE is degraded in the body by the same metabolic pathway as endogenous hyaluronic acid.

Mode of Action
The body's hyaluronic acid constitutes a natural part of the cartilage and acts in the joints both as a lubricant of cartilages and ligaments and as a shock absorber. Injections of hyaluronic acid in the joint to restore the viscosity and elasticity of the synovial fluid and to enhance the lubrication.

Dosage
DUROLANE is a single injection, single dose preparation and should only be injected once per treatment course. The recommended dose is 3 mL per joint. The recommended dose is 1-2 mL for intermediate joints (e.g., elbow, ankle) and approximately 1 mL for small synovial joints (e.g., wrist, finger, toes).

Indications
Symptomatic treatment of mild to moderate knee or hip osteoarthritis. In addition, DUROLANE has been approved for the symptomatic treatment associated with mild to moderate osteoarthritis in the ankle, shoulder, elbow, wrist, finger and toes. DUROLANE is also indicated for pain following joint arthroscopy in the presence of osteoarthritis within three months of the procedure.

Intended Use
DUROLANE is intended to treat pain and improve function of synovial joints affected by osteoarthritis.

Intended Population
The product is intended to be used in an adult population with hip osteoarthritis. DUROLANE has not been tested in pregnant or lactating women or in children.

Clinical Benefits
DUROLANE provides a non-surgical option to treat osteoarthritis with moderate to severe pain. DUROLANE is used for the symptomatic treatment of mild to moderate osteoarthritis in the ankle, shoulder, elbow, wrist, finger and toes. The potential to delay joint replacement surgery with a single injection.

Contraindications
DUROLANE should not be injected if the synovial joint is infected or if there is an active skin infection at the injection site. DUROLANE should not be injected if there is an active skin disease or infection present at or near the injection site.

• DUROLANE should not be injected intravascularly or extra-articularly into the synovial tissues or capsule.
• The anesthetic agents used in DUROLANE are known to be sensitive to hyaluronic acid based products.
• DUROLANE should not be injected in patients with pre-existing chondrocalcosis as injection may lead to an increase in the risk of the condition.

Warnings
• Do not reutilize DUROLANE as this may damage the product.
• Pain, skin necrosis (Nicolau Syndrome), pulmonary embolism or suboptimal treatment results may occur with overuse of DUROLANE. DUROLANE should be used with caution in patients with a history of bleeding disorders.

• A separate syringe of DUROLANE must be used for each individual joint to be treated.
• As with any invasive joint procedure there is a small risk of infection.
• Local anaesthetics should not be used if the patient is known to be allergic or sensitive to local anaesthetics.

• Injection under fluoroscopic control and with the use of a contrast medium should be used if the patient is known to be allergic or sensitive to the contrast medium.
• Increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.

Precautions
DUROLANE should be used with caution in patients with venous or lymphatic stasis present in the leg.
• A separate syringe of DUROLANE must be used for each individual joint to be treated.
• As with any invasive joint procedure there is a small risk of infection.

• Local anaesthetics should not be used if the patient is known to be allergic or sensitive to local anaesthetics.
• Injection under fluoroscopic control and with the use of a contrast medium should be used if the patient is known to be allergic or sensitive to the contrast medium.

• Increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.

Adverse Events
The most commonly reported adverse effects (e.g., complication associated with the use of DUROLANE and hyaluronic acid based preparations) in general include transient pain, swelling and/or stiffness localized to the joint. Such reactions are usually mild and resolve in intensity, occasionally requiring treatment with analgesics.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or patient is established.

Interactions
The safety and effectiveness of DUROLANE concomitantly with other intra-articular injectables have not been studied.

Administration
The following section provides general guidance, along with applicable warnings and/or precautionary measures that should be followed for the intra-articular injection procedure.

General administration precautions
• DUROLANE should only be injected by an authorized physician (or in accordance with local legislation), familiar with intra-articular injection techniques and with the correct aseptic technique.

• DUROLANE should be injected using strict aseptic technique.
• DUROLANE should be injected into the joint cavity only.
• Intra-articular injection in certain synovial joints will require guidance to ensure accurate placement and avoidance of damage to adjacent vital structures.
• The route for intra-articular injection with or without image guidance should be used so that damage to adjacent vital structures is avoided.

• The injection site should be swabbed with alcohol or other suitable antiseptic solution before use.
• The injection should not be used concomitantly with de-identified contrast medium or any other contrast agent for skin preparation because sodium hyaluronate can precipitate with contrast agents.

• Remove joint effusion, if present, before injecting DUROLANE. The same needle should be used for both removal of effusion and injection of DUROLANE.
• The recommended needle size is 18 to 22 G and with adequate length to reach the joint space.

• Use of smaller needle sizes increases pressure required to deliver the product.

Additional information for treatment of synovial joints requiring image guidance
• The injection site in the hip joints should be given under fluoroscopic control (preferably with a contrast medium) or ultrasonographic control in order to ensure correct location of the injection into the joint cavity.

• Guidance of other synovial joints is at the discretion of the treating physician.
• The effectiveness of DUROLANE should be assessed by clinical examination and/or imaging techniques.

• The recommended needle size is 18 to 22 G and with adequate length to reach the joint space.
• Use of smaller needle sizes increases pressure required to deliver the product.

Please inform your patient that:
• As with any invasive joint procedure it is recommended to avoid strenuous activity (e.g. tennis, jogging or long walks) for 48 hours after the injection.
• The effectiveness of DUROLANE following arthroscopic procedures for diagnosis or examination purposes only or for treatment of concomitant osteoarthritis of the joint has not been established.

Please inform your patient that:
• As with any invasive joint procedure it is recommended to avoid strenuous activity (e.g. tennis, jogging or long walks) for 48 hours after the injection.
• The effectiveness of DUROLANE following arthroscopic procedures for diagnosis or examination purposes only or for treatment of concomitant osteoarthritis of the joint has not been established.

How Supplied
DUROLANE is supplied in a 3 mL glass syringe with a Luer-Lock fitting, packed in a blister pack. The contents of the syringe are sterile. The exterior of the syringe is not sterile.

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For package insert Information Summary of Safety and Clinical Performance (SSCP) prior to EU/UK approval go to: www.durolane.com

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