DUROLANE INSTRUCTIONS FOR USE

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Contents

Each ml contains:

Hyaluronic acid stabilized	20 mg
Phys sodium chloride solution, pH7	q.s.

Description

DUROLANE* is intended to be used for intra-articular injection for the symptomatic treatment of mild to moderate knee or hip osteoarthritis.

DUROLANE contains 20 mg/ml of stabilized non-animal hyaluronic acid in buffered physiological sodium chloride solution pH 7. DUROLANE is a sterile, transparent viscoelastic gel supplied 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 the tissues of the body, with particularly high concentrations in the synovial fluid and the skin. DUROLANE is composed of biosynthetically produced hyaluronic acid which 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 synovial fluid and acts in the joints both as a lubricant of cartilage and ligaments and as a shock absorber. Injections of hyaluronic acid in the joint to restore the viscosity and elasticity can diminish the pain and improve the mobility of the joint.

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 knee or hip.

Indications

Symptomatic treatment of mild to moderate knee or hip osteoarthritis.

Contraindications

None known.

Warnings

- DUROLANE should not be injected if the synovial joint is infected or severely inflamed.
- 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 or in the synovial tissues or capsule.
- Do not resterilize DUROLANE as this may damage the product.

Precautions

- DUROLANE should be used with caution in patients with venous or lymphatic stasis present in the leg.
- DUROLANE has not been tested in pregnant or lactating women or in children.
- 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.
- DUROLANE should not be injected if the patient is known to be sensitive to hyaluronic acid based products.
- 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 not be made if the patient is known to be allergic or sensitive to the contrast medium.
- In clinical studies, reinjections in the knee have not been studied with a shorter interval between first and second injection than 6 months.
- Increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.
- DUROLANE should be used with caution in patients with pre-existing chondrocalcinosis as injection may lead to an acute attack of the condition.

Adverse Events

The majority of the reported adverse reactions in clinical studies of the knee and hip were described as transient pain, swelling and/or stiffness localized to the joint. These adverse reactions were of mild or moderate intensity and only occasionally required treatment with painkillers or NSAID.

Adverse events must be reported to the local Bioventus representative.

Interactions

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

Administration

General administration information

- DUROLANE should only be injected by an authorized physician (or in accordance with local legislation), familiar with intra-articular injection technique for the synovial joint intended to be treated, and in facilities well suited for intra-articular injections.
- 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 image 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 chosen so that damage to adjacent vital structures is avoided.
- The injection site should be swabbed with alcohol or other suitable antiseptic solution before injection.
- 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.
- Use of smaller needles increases pressure required to deliver the product.

Additional information for treatment of synovial joints requiring image guidance

- The intra-articular injection in the hip should be given under fluoroscopic control (preferably with a contrast medium) or ultrasonographic control in order to assure correct location of the needle in the joint cavity.
- Injection discomfort can be minimized by use of topical freezing agents or subcutaneously delivered local anaesthetics.
- Image guided injection should only be performed by physicians experienced in this type of administrations.

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) the first two days after the injection.
- Some transient reactions related to the injection of DUROLANE, such as pain and/or swelling/ stiffness of mild to moderate intensity during the first week following the injection can be anticipated. If the symptoms last for more than a week a physician should be contacted.

Performance

- Clinical studies of DUROLANE for osteoarthritis of the knee and hip indicate significant mean benefit, such as improvement in knee and hip pain and physical function versus baseline values at 6 months post treatment.
- Studies investigating repeated treatment in the knee 6 months following the initial injection did not give rise to an increased rate of adverse events.
- Controlled trials of DUROLANE in knee osteoarthritis indicates significant benefits in responder rate over saline and non-inferior results as compared to corticosteroid in a widely adopted effectiveness population of patients.
- The half life of DUROLANE in human knees is approximately four (4) weeks.

How Supplied

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

DUROLANE is intended for single use and should not be re-sterilized. It should be used immediately after the syringe has been removed from its packaging. If the blister package or syringe is opened or damaged, do not use.

The syringe and any unused material must be discarded immediately after the treatment session and must not be reused due to risk of contamination of the unused material and the associated risks including infections. Disposal should be in accordance with accepted medical practice and applicable national, local or institutional guidelines.

Shelf life and Storage

DUROLANE should be stored, in its original packaging, up to 30 °C. The expiry date is indicated on the package and should not be used beyond that date. Protect from freezing.

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IF THE PACKAGE IS DAMAGED, DO NOT USE

For package insert information visit:
www.durolane.com

90-14247-01

bioventus®

DUROLANE™
hyaluronic acid, stabilized single injection

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Symbols on packaging

	Attention, see instructions for use
	Single use only. Do not reuse
	Expiration Date
LOT	Lot number
STERILE	Sterile. The contents of the syringe have been sterilized by using moist heat. The exterior of the syringe is not sterile.
	Manufacturer
	Temperature limitation.