DUROLANE INSTRUCTIONS FOR USE

GB

Contents
Each ml contains:

Hyaluronic acid, stabilized	20 mg
Phys. sodium chloride solution, pH 7	q.s.

Description
DUROLANE* is a CE-marked medical device fulfilling the requirements of MDD 93/42/EEC.

DUROLANE contains 20 mg/ml of non-animal stabilized hyaluronic acid (NASHA) 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 belongs to a group of very few substances which are 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 stablized. 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 lubricant of cartilage and ligaments and as a shock absorber. It is known that the synovial fluid in joints affected by osteoarthritis has a much lower viscosity and elasticity than in healthy joints. Injections of hyaluronic acid in the joint to restore the viscosity and elasticity can diminish the pain and improve the mobility of the joint.

Indications
Symptomatic treatment of mild to moderate knee osteoarthritis.

Contraindications
DUROLANE should not be injected:
- If the patient is known to be sensitive to hyaluronic acid based products.
- If there is a skin disease or infection present at or near the injection site.
- If the knee joint is infected or severely inflamed.

Precautions
- DUROLANE should be used with caution in patients with venous or lymphatic stasis present in the leg.
- DUROLANE should not be injected intravascularly or extra-articularly or in the synovial tissues or capsule.
- DUROLANE has not been tested in pregnant or lactating women or in children.
- If treatment is bilateral, a separate syringe of DUROLANE must be used for each knee.
- As with any invasive joint procedure there is a small risk of infection when injecting DUROLANE.
- 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.

Anticipated Side-effects
The majority of the reported adverse reactions in clinical studies were described as transient pain, swelling and/or stiffness localized to the knee and were of mild or moderate intensity with a median duration of one week.

Adverse Events
In a few patients symptoms of pain and/or swelling/stiffness localized to the knee lasted for more than 3 weeks but in these cases the observed symptoms were not distinguishable from fluctuations in the underlying osteoarthritis condition.

None of the adverse reactions were interpreted as acute inflammatory arthritis or allergic reactions and they did not need medical attention in the form of surgical intervention, systemic or intra-articular steroids or antibiotics.

Adverse events must be reported to the local Q-Med representative.

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

Dosage
DUROLANE is a **single dose** preparation and should only be injected once per treatment course. The recommended dose is 3 ml (one syringe) per knee joint.

Administration
- DUROLANE should only be injected by an authorized physician or in accordance with local legislation.
- DUROLANE should be injected using strict aseptic technique, taking particular care when removing the protective seal from the syringe and assembling the needle.
- The injection site should be swabbed with alcohol or other suitable antiseptic solution before injection.
- An appropriate needle should be used. The recommended needle size is 18 to 22 G.
- Remove joint effusion, if present, before injecting DUROLANE. The same needle should be used for both removal of effusion and injection of DUROLANE.
- Inject into the joint space only.
- The syringe, the needle and any unused material must be discarded after the treatment session.

Performance
- Clinical data indicate relief of symptoms from knee osteosarthritis for at least three months. Patients were retreated after 6 months. Retreatment did not give rise to an increased rate of adverse events.
- The half life of the product in human knees is approximately four (4) weeks, meaning that about one-fourth of the dose remains 8 weeks.

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.

How supplied
DUROLANE is supplied in a 3 ml glass syringe, packed in a blister pack. The contents of the syringe, non-animal stabilized hyaluronic acid gel, are sterile.

Shelf life and Storage
DUROLANE should be stored in its original packaging at a temperature of 2 °C – 25 °C. The expiry date is indicated on the package. Protect from sunlight and freezing.

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IF THE PACKAGE IS DAMAGED, DO NOT USE

Symbols on packaging

	Refer to instructions for use
	For single use. Sterility is only guaranteed if the syringe is intact.
	Storage temperature
	Use until date
	Lot number
	Sterile. The contents of the syringe have been sterilized by using moist heat.
	CE-marked according to MDD 93/42/EEC; 0344 is No of notified body.

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