Instructions for proper handling and administration of DUROLANE®

DUROLANE®
hyaluronic acid, stabilized single injection

Complete Indications, Contraindications, Warnings and Precautions including additional product information can be found in DUROLANE Labeling. Selected instructions on the proper handling of the syringe, product administration and precautions are shown below. This document is not meant to replace the product's Packaging Insert.

Dosage

- DUROLANE is a single injection, single dose preparation and should only be injected once per treatment course.

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

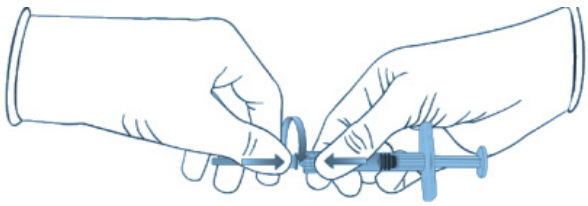
- A separate syringe of DUROLANE must be used for each individual joint to be treated.
- Increase in injection pressure may indicate incorrect extra-articular placement of the needle or overfilling of the joint.

Shelf life and Storage

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

Administration

- 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.
- 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.
- Assembly of the syringe and needle:
  - *Twist the tip cap before pulling it off, as this will minimize product leakage.*
  - *To ensure a tight seal and prevent leakage during administration, secure the needle tightly while firmly holding the Luer-lock. Use the thumb and forefinger to hold firmly around both the glass syringe and the Luer-lock adaptor. Grasp the needle shield or hub, if using cannula, with the other hand. To facilitate proper fastening, both push and rotate firmly.*



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How Supplied

- DUROLANE is supplied in a 1 mL or 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.
- 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.

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 the EU for the symptomatic treatment associated with mild to moderate osteoarthritis pain in the ankle, shoulder, elbow, wrist, fingers, and toes.

DUROLANE SJ (1 mL): 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.**

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