1. Warnings and precautions that the patient should be aware of

Indications
Pain and decreased articular mobility associated with traumatic or degenerative changes including osteoarthritis.

Contraindications
The medical device should not be used in patients:
- with known hypersensitivity to any of the components of the product;
- with septic arthritis;
- with dermatosis at the injection site;
- taking anticoagulants.

Precautions
All safety precautions during procedure should be taken to prevent occurrence of septic arthritis.
Medical device intended only for intra-articular injections.
Do not concomitantly use disinfectants containing quaternary ammonium salts for skin preparation as hyaluronan can precipitate in their presence.
Children, pregnant or nursing women should not be treated with this medical device as there are no clinical data available on its use in these patients.
Medical device should not be used if a pre-filled syringe is damaged.
Medical device must be used before the expiration date indicated on the packaging.
Do not resterilise.
The pre-filled syringe is intended for single-use only.
Store at temperature between +2°C and +25°C. Keep away from sunlight. Protect from moisture.
Medical device must be kept out of the reach of children.

Potential side effects
Biocompatibility studies have confirmed the high safety of the medical device.
Transient local reactions such as pain, redness and swelling may occur after intra-articular injection. These effects can be reduced by cooling the injection site for 5 to 10 minutes after the injection. Simultaneous oral intake of analgesics and anti-inflammatory drugs (NSAIDs) may be beneficial for pain relief.

2. Information on the expected service life of the device
The therapy consists of a series of three intra-articular injections, administered at weekly intervals. The beneficial effects of the treatment last for at least six months. The treatment cycle may be repeated, if required.

3. Information on safe use
Disinfect the skin at the site of the planned injection. Take the pre-filled syringe from the blister, unscrew the Luer-lock closure and screw a suitable sterile needle onto

the syringe. Remove air bubbles before injection. After injection, place the used syringe in a medical waste container and dispose of it. In case of intra-articular effusion, it is recommended to remove it before the administration of the device.

4. Adverse events reporting

In case of serious adverse events, it should be reported to the manufacturer and to the Member State competent authority. By reporting adverse events, more information on safety of the medical device can be gathered.