**Mode of Action**

Synovial fluid, which is viscoelastic due to the presence of hyaluronic acid, is found in all synovial joints where it ensures normal, painless movement due to its lubricating and shock-absorbing properties. It is also responsible for the nutrition of the cartilage. In degenerative joint disorders such as osteoarthritis, the viscoelasticity of the synovial fluid is markedly reduced thereby decreasing its lubricating and shock-absorbing functions. This increases mechanical loading of the joint and cartilage destruction which ultimately results in pain and restricted mobility of the affected joint. Supplementing this synovial fluid with intra-articular injections of highly purified hyaluronic acid can ameliorate the viscoelastic properties of synovial fluid. This improves its lubricating and shock-absorbing functions and reduces mechanical overload of the joint. As a rule this results in a decrease in pain and an improvement in joint mobility which may last for several months after a treatment cycle.

**Package Content**

Each package contains one disposable graduated and pre-filled syringe with **XXXXX** gel.

One syringe contains 1.0 ml of **XXXXX** . The content of **XXXXX** syringe is sterile using aseptic processing techniques. The accuracy of syringe graduations is ±0.020 ml.

**XXXXX** package is supplied with instructions for use, two patient labels and one 21G needles.

**Dosage and Administration**

Inject **XXXXX** into the affected joint once a week for a total of 1–3 injections. Several joints may be treated at the same time. Depending on the severity of the joint disease the beneficial effects of a treatment cycle may last at

least six months. Repeat treatment cycles may be administered as required. In case of joint effusion, it is advisable to reduce the effusion by aspiration, rest, application of an ice pack and/or intraarticular corticosteroid injection.

**Indication for Use**

**XXXXX** is indicated for pain and restricted mobility in degenerative and traumatic changes of the knee joint and other synovial joints (such as shoulder, ankle and metacarpal joints).

Inject **XXXXX** into the affected joint 1 (one) injection every 6 (six) months. Several joints may be treated at the same time

**Contra-indications**

**XXXXX** is contraindicated:

* For patients with a known sensitivity to any of the product components.
* For patients suffering from an acute or chronic inflammation or infection in the area to be treated.
* In patients with a tendency to develop inflammatory skin conditions or hypertrophic scarring.
* For patients with unhealthy or poorly vascularized tissue or with systemic disorders affecting wound healing.
* For patients suffering from skin disease or abnormal skin conditions.
* For patients with a history of anaphylactic reactions.
* For use in regions containing foreign bodies (e.g., silicone, other particulate materials).
* For patients with known systemic bleeding disorders.
* For patients with autoimmune diseases.
* For patients suffering from porphyria.
* For patients suffering from untreated epilepsy.
* For use in breastfeeding or pregnant women.