

PATIENT INFORMATION

Nuflexxa

(1% Sodium Hyaluronate)

WHAT IS NUFLEXXA?

Nuflexxa is a gel-like, elastic, sterile product containing natural, highly purified sodium hyaluronate. Hyaluronan (hye-a-loo-ROE-nan), as it is also known, is a natural substance found in the body and is present in particularly high amounts in joint tissues and in the fluid that fills the joints. The body's own hyaluronan acts like a lubricant and a shock absorber in the joint, and is needed for the joint to function properly. Osteoarthritis is a condition that involves the wearing down of cartilage (the protective covering on the ends of your bones). In osteoarthritis, there may not be enough hyaluronan, and there may be a decrease in the quality of the hyaluronan in joint fluid and tissues.

Nuflexxa comes in pre-filled syringes containing 2 mL (about half a teaspoon) of product. Nuflexxa is given by injection directly into the knee joint.

WHAT IS NUFLEXXA USED FOR?

Nuflexxa is used to relieve knee pain due to osteoarthritis. It is used for patients who do not get enough relief from simple pain medications such as acetaminophen or from exercise and physical therapy.

WHAT ARE THE BENEFITS OF NUFLEXXA?

A clinical study involving 321 patients between the ages of 50 and 80 years of age with knee pain due to osteoarthritis was performed in Germany. The study investigated the safety and effectiveness of Nuflexxa. The patients were placed in one of two groups. One group was given an injection of Nuflexxa into one or both knee joints once a week for 3 weeks. The second group was given an injection of another commercially available sodium hyaluronate once a week for 3 weeks. Pain, stiffness and function of the knee joint and patients' and doctors' judgment of the success of treatment were measured for 12 weeks. Patients with osteoarthritic knee joint pain, who had not obtained pain relief with other medications, experienced pain relief from the Nuflexxa injections into the knee joint, similar to those patients who received injections of the other sodium hyaluronate.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

If you have osteoarthritis, there are several things you can do besides getting Nuflexxa injections. These include:

Non-drug treatments

- avoiding activities that cause pain in your knee
- exercise
- physical therapy
- removal of excess fluid from the knee

Drug therapy

- pain medications such as acetaminophen and narcotics
- drugs that reduce inflammation, such as aspirin and other nonsteroidal anti-inflammatory agents (NSAIDS) such as ibuprofen and naproxen
- corticosteroids that are injected directly into the joint

ARE THERE ANY REASONS WHY YOU SHOULD NOT TAKE NUFLEXXA?

- You should not take this product if you have had any previous allergic reaction to Nuflexxa or hyaluronan products
- You should not have an injection into the knee if you have a knee joint infection or skin diseases or infections around the injection site.

THINGS YOU SHOULD KNOW ABOUT NUFLEXXA:

- Nuflexxa is a very highly purified product extracted from bacterial cells
- Nuflexxa is only for injection into the knee, performed by a qualified doctor.
- Consult your physician if you are allergic to hyaluronate products
- After you receive the injection, you may need to avoid activities such as jogging, tennis, heavy lifting, or standing on your feet for a long time, i.e, more than one hour.
- The safety and effectiveness of repeat treatment cycles of Nuflexxa have not been established.
- Nuflexxa has not been tested in pregnant women or women who are nursing. You should tell your doctor if you think you are pregnant or nursing a child.
- The safety and effectiveness of Nuflexxa have not been shown in children under 18 years of age.

POSSIBLE COMPLICATIONS:

- Side effects sometimes seen when Nuflexxa is injected into the knee joint were pain, swelling, skin irritation and tenderness. These reactions were generally mild and did not last long.
- Rare cases of back pain, blood pressure increase, fatigue, nausea and burning, itching, and/or tingling sensation were seen.
- If any of the above symptoms or signs appears after you are given Nuflexxa, or if you have any other problems, you should call your doctor.

HOW IS NUFLEXXA GIVEN?

Your doctor will give you your injection of Nuflexxa (20 mg/ 2mL) into your knee joint once a week, for a total of three injections.

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