

EUFLEXXA®

(1% Sodium hyaluronate)

Consumer Medicine Information

WHAT IS EUFLEXXA?

EUFLEXXA is a gel-like, elastic, sterile product containing natural, highly purified hyaluronan (hye-a-loo-ROE-nan), (also known as sodium hyaluronate). Hyaluronan 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.

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

WHAT IS EUFLEXXA USED FOR?

EUFLEXXA is used to relieve joint pain caused by medically diagnosed osteoarthritis of the knee joint or other synovial joints. EUFLEXXA helps to lubricate the joint, allows for greater mobility and flexibility of the treated joint, and reduces pain in the affected joint.

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

If you have osteoarthritis, there are several things you can do besides getting EUFLEXXA injections.

These include:

Non-drug treatments

- avoiding activities that cause pain in your affected knee or other synovial joint
- appropriate exercise
- physical therapy
- removal of excess fluid from the affected knee or other synovial joint.

Drug therapy

- pain medications such as paracetamol 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 EUFLEXXA?

- You should not take this product if you have had any previous allergic reaction to EUFLEXXA or hyaluronan products.
- You should not have an injection into the affected knee joint or other synovial joint if you have a joint infection or

skin diseases or infections around the injection site.

THINGS YOU SHOULD KNOW ABOUT EUFLEXXA:

- Always read the label.
- Your doctor will advise you whether EUFLEXXA is suitable for you/your condition.
- EUFLEXXA is a very highly purified product extracted from bacterial cells.
- EUFLEXXA is only for injection into the affected knee joint or other synovial joint, performed by a qualified doctor.
- Consult your physician if you are allergic to hyaluronan 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 EUFLEXXA have not been established.
- EUFLEXXA 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 EUFLEXXA have not been shown in children under 18 years of age.

POSSIBLE COMPLICATIONS:

- Your doctor has weighed the risks of using this product against the benefits they expect it will have for you. Do not be alarmed by the following list of possible side effects. You may not get any of them. Ask your doctor any questions you may have.
- Side effects are sometimes seen when EUFLEXXA is injected into the affected knee joint or other synovial joint. Associated symptoms such as itching, redness, swelling and pain may occur at the injection site. Application of ice to the treated joint may relieve these symptoms. These symptoms generally decrease within a short period.
- Other effects occasionally experienced were nausea, fatigue, tenderness, back pain, skin irritation, blood pressure increased and burning, itching, and/or tingling sensation.
- Tell your doctor if any of the above symptoms or signs appears after you are given EUFLEXXA.
- Tell your doctor if you do not feel well or if you notice any other effects, even if they are not on this list.

HOW IS EUFLEXXA GIVEN?

Use only as directed. EUFLEXXA must be administered by a doctor/qualified medical personnel.

Your doctor will give you your injection of 1 to 2 mL EUFLEXXA (20 mg/ 2 mL) into your affected knee joint or other synovial joints once a week, for a total of three injections.

If symptoms persist see your doctor.

If you have any questions or problems, talk to your doctor.

INGREDIENTS

Each 1 mL of EUFLEXXA contains:

- Sodium hyaluronate 10 mg
- Sodium chloride 8.5 mg
- Disodium hydrogen phosphate dodecahydrate 0.56 mg
- Sodium dihydrogen phosphate dehydrate 0.05 mg
- Water for injections.

HOW EUFLEXXA IS STORED

EUFLEXXA® should be kept in the outer carton until it is time to use it. This helps protect it from light. Keep EUFLEXXA in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Keep EUFLEXXA® in a refrigerator in a way children cannot get to it. EUFLEXXA may be removed from refrigeration within the product shelf life and stored at room temperature (15°C - 25°C) for up to six (6) months.

MANUFACTURED BY:

Bio-Technology General (Israel) Ltd., Be'er Tuvia
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AUSTRALIAN SPONSOR

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