

EUFLEXXA®

(1% Sodium hyaluronate)

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 substance found naturally in the body and is present in particularly high amounts in joint tissues and the synovial fluid (the fluid that fills the joints). Hyaluronan acts as a lubricant and shock absorber for the joints and allows the cartilage, the protective surfaces of your bones, to glide over each other smoothly. This helps the joints to work properly.

Osteoarthritis is a condition that involves the wearing down of cartilage and a reduction in the amount of hyaluronan in the joint fluid and tissues. In osteoarthritis, the quality of the hyaluronan in the joints may be reduced and there may not be enough hyaluronan to help the joints work properly.

WHAT IS EUFLEXXA USED FOR?

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

WHAT OTHER TREATMENTS ARE AVAILABLE FOR OSTEOARTHRITIS?

If you have been diagnosed with osteoarthritis, there are several things you can do besides getting EUFLEXXA injections. These include:

Non-drug treatments:

- avoiding activities that cause a lot of 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 nonsteroidal anti-inflammatory agents (NSAIDs) including aspirin, 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, 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 and 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 doctor if you are allergic to hyaluronan products or any of the ingredients listed in "INGREDIENTS" below.
- 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 if you are 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. Ask your doctor any questions you may have.

Tell your doctor if you notice any of the following after you are given EUFLEXXA:

- Itching, redness, swelling at the injection site. Application of ice to the treated joint may help to relieve these symptoms. These symptoms are usually short-lived.
- feeling sick (nausea)
- feeling tired (fatigue)
- tenderness
- back pain
- skin irritation
- increased blood pressure
- burning, itching, and/or tingling sensation

Tell your doctor if you notice anything that is making you feel unwell. Other side effects not listed above may occur in some people.

Any serious incident that occurs in relation to the product should be reported to the manufacturer and to the Therapeutic Goods Administration (TGA) at www.tga.gov.au/reporting-problems.

HOW IS EUFLEXXA GIVEN?

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

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

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

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 original packaging until it is time to use it. This helps protect it from light. Store EUFLEXXA in a refrigerator where the temperature stays between 2°C and 8°C. Do not freeze. Keep out of reach of children.

EUFLEXXA may be removed from the refrigerator and stored at room temperature (15°C - 25°C) for up to six (6) months within the product shelf-life.

MANUFACTURED BY:

Bio-Technology General (Israel) Ltd.
Be'er Tuvia Industrial Zone,
Kiryat Malachi, 8310402, Israel.

AUSTRALIAN SPONSOR

Ferring Pharmaceuticals Pty Ltd
Suite 2, Level 1, Building 1
20 Bridge Street PYMBLE NSW 2073

EUFLEXXA and FERRING are registered trademarks of Ferring B.V.

DATE OF PREPARATION

23 March 2020