EUFLEXXA®
(1% Sodium hyaluronate)

CONTENT

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 q.s.

DESCRIPTION

EUFLEXXA is a viscoelastic, sterile solution of highly purified, high molecular weight (2.4-3.6 million daltons) sodium hyaluronate in phosphate-buffered saline. EUFLEXXA is a highly purified physiological product. It is a polysaccharide consisting of a repeating disaccharide of N-acetylglucosamine and sodium glucuronate, linked by alternating β-1,3 and β-1,4 glycosidic bonds.

Hyaluronate can be found in synovial fluid, in the vitreous and aqueous humor of the eye, in skin and in the umbilical cord. The contents of the EUFLEXXA syringe are sterile (aseptic filling).

INDICATIONS

EUFLEXXA is indicated for the treatment of pain caused by osteoarthritis of the knee joint or other synovial joints. EUFLEXXA aids in lubrication of the joint, allows for greater mobility and flexibility of the treated joint, and reduces pain in the affected joint.

CONTRAINDICATIONS

Do not use EUFLEXXA to treat patients who have a known hypersensitivity to hyaluronate preparations or patients with joint infection, infections in the injection site area or skin diseases.

PRECAUTIONS

EUFLEXXA is to be administered only by qualified medical personnel. Remove any joint effusion before injection.

The efficacy and tolerance of an injection in conjunction with other intra-articular treatments have not been established.

EUFLEXXA has not been tested on pregnant women, lactating women and children under 18 years.

Since EUFLEXXA is a substance purified from bacterial cells, the presence of exceedingly minute quantities of impurities cannot be totally excluded. The physician should be aware of potential risks associated with the injection of biological substances.

Protect from light. Do not use after expiry date. Do not inject intravascularly. Do not re-use; dispose of the syringe after use. Do not use if the blister package or the syringe is opened or damaged.

DOSAGE AND ADMINISTRATION

EUFLEXXA is intended for injection into the synovial space. Usually a dose of 1 mL or 2 mL is injected into the affected joint at weekly intervals for a total of three injections. For the best effect, all three injections must be administered.

Bring the EUFLEXXA syringe to room temperature before use. Use aseptic technique when handling the syringe and administering the injection. See the Instructions for Use section for details of preparing the syringe for use. If the patient presents with effusion, the effusion should be removed before EUFLEXXA is injected into the joint. Inject the contents of the syringe into the joint being treated. Discard any unused EUFLEXXA. Each EUFLEXXA syringe is intended for single use only. The syringe should be used immediately after the individual syringe blister is opened. If treatment is being administered to more than one joint, use a separate syringe for each joint.

For patients who respond to treatment, the effect of treatment lasts for at least twenty-six weeks.

Do not use EUFLEXXA if the package or the syringe is opened or has been tampered with or damaged.

INCOMPATIBILITIES

Mixing of quaternary ammonium salts such as benzalkonium chloride with sodium hyaluronate solutions results in formation of a precipitate.

EUFLEXXA should not be administered through a needle previously used with medical solutions containing benzalkonium chloride.

Do not use disinfectants for skin preparation that contain quaternary ammonium salts.

ADVERSE REACTIONS

In clinical trials, the most common events were arthralgia and joint swelling.

Other events experienced were effusion, nausea, fatigue, non-specified tenderness, back pain, paraesthesia, skin irritation and non-specified hypertension. 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.

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

INTERACTIONS
None currently known.

PRESENTATION
EUFLEXXA is supplied in 2.25 mL nominal volume, disposable, pre-filled glass syringes containing 2 mL of EUFLEXXA. Available in a box of 3 syringes. The contents of the syringe are sterile and non-pyrogenic.

SHELF LIFE
3 years

STORAGE INSTRUCTIONS
Store in a cold dark place (2°C - 8°C). Do not freeze. 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 Industrial Zone,
Kiryat Malachi, 8310402, Israel.

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

DATE OF MOST RECENT AMENDMENT
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