



VIVIAN E. LEE/ELSEVIER GLOBAL MEDICAL NEWS

# Custom-Made Foot Orthotics Relieve Some Arthritis Pain

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London Bureau

Researchers found data supporting the benefit of custom foot orthotics for some.

Custom-made foot orthotics can reduce foot pain caused by rheumatoid arthritis, pes cavus, and hallus vagus, according to a Cochrane Collaboration meta-analysis. The authors stressed, however, that

there are very few high-quality studies evaluating the use of orthotics to treat such conditions, weakening the clinical relevance of their conclusions.

The researchers evaluated a total of 11 randomized controlled trials and controlled clinical trials, which together had 1,332 subjects. The strongest evidence supporting the use of cus-

tomized orthotics was in the treatment of painful pes cavus (high arch).

They also found evidence supporting orthotic use to treat foot pain associated with juvenile idiopathic arthritis, rheumatoid arthritis, plantar fasciitis, and hallux valgus.

"Custom foot orthoses can be an effective treatment for a variety of conditions, but there are still many causes of foot pain for which the benefit of this treatment is unclear," Fiona Hawke, the lead researcher, who works at the Central Coast campus of the University of Newcastle (Australia), said in a written statement.

"There is also a lack of data on the long-term effects of treating with orthoses."

► **Painful pes cavus.** The researchers found a single study that showed custom orthotics were superior to sham orthotics at 3 months in treating 154 patients with this disorder.

Those wearing custom orthoses showed a statistically significant weighted mean difference of 10.9 points on the pain domain of the foot health status questionnaire and 11 points in the function domain (Cochrane Database Syst. Rev. 2008 July 15 [Epub doi: 10.1002/14651858.CD006801.pub2.]).

► **Juvenile idiopathic arthritis.** A single study of 33 children showed that custom foot orthotics were linked to significant improvements at 3 months in pain, function, and disability, compared with a standardized intervention (supportive shoes).

Weighted mean improvements of 19.2 on the pain scale of the foot function index, 19.4 on the index's activity limitation scale, and 18.6 on the disability scale were reported.

► **Rheumatoid arthritis.** A single study with 101 subjects found foot orthotics were more effective than no intervention in reducing rear foot pain after 30 months.

► **Plantar fasciitis.** A study of 92 subjects assessed at 3 and 12 months demonstrated a statistically significant improvement in foot pain-related function for those who used custom orthotics to treat plantar fasciitis, compared with those using sham orthoses.

Treated subjects reported a weighted mean improvement of 10.4 at both time points on the foot health status questionnaire.

The investigators did not measure a statistically significant improvement over standard interventions, however, and found that customized orthotics were less effective than stretching and mobilization over 2 weeks.

► **Painful bunions with hallux valgus.** Foot orthotics were shown to be more effective than no intervention over 6 months in a study of 138 subjects, with a weighted mean improvement of 9 on the 100-mm visual analog scale.

That study did not find a statistically significant improvement over 12 months, however. ■



UNIQUE NATIONAL  
HCPCS CODE  
**J7323**

## BRIEF SUMMARY

Please consult package insert for full Prescribing Information.

## INDICATION

EUFLEXXA® (1% sodium hyaluronate) is indicated for the treatment of pain in osteoarthritis (OA) of the knee in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics (e.g., acetaminophen).

## CONTRAINDICATIONS

- Do not use EUFLEXXA® to treat patients who have a known hypersensitivity to hyaluronan preparations
- Do not use EUFLEXXA® to treat patients with knee joint infections, infections or skin disease in the area of the injection site

## WARNINGS

- Mixing of quaternary ammonium salts such as benzalkonium chloride with hyaluronan 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
- Do not inject intravascularly because intravascular injection may cause systemic adverse events

## PRECAUTIONS

### General

- Patients having repeated exposure to EUFLEXXA® have the potential for an immune response; however, this has not been assessed in humans
- Safety and effectiveness of injection in conjunction with other intra-articular injectables, or into joints other than the knee has not been studied
- Remove any joint effusion before injecting
- Transient pain or swelling of the injected joint may occur after intra-articular injection with EUFLEXXA®
- Do not use after expiration date
- Protect from light
- Do not re-use—dispose of the syringe after use
- Do not use if the blister package is opened or damaged

### Information for Patients

- Transient pain and/or swelling of the injected joint may occur after intra-articular injection of EUFLEXXA®
- As with any invasive joint procedure, it is recommended that the patient avoid any strenuous activities or prolonged (i.e., more than 1 hour) weight-bearing activities such as jogging or tennis within 48 hours following intra-articular injection
- The safety and effectiveness of repeated treatment cycles of EUFLEXXA® have not been established

## ADVERSE EVENTS

Adverse event information regarding the use of EUFLEXXA® as a treatment for pain in OA of the knee was available from two sources; a multicenter clinical trial conducted in Germany and a single center clinical trial that was conducted in Israel.

### Multicenter Clinical Investigation

This clinical investigation was a prospective randomized, double blinded, active control (commercially available hyaluronan product) study conducted at 10 centers. Three hundred twenty-one patients were randomized into groups of equal size to receive either EUFLEXXA® (n=160) or the active control (n=161). A total of 119 patients reported 196 adverse events; this number represents 54 (33.8%) of the EUFLEXXA® group and 65 (44.4%) of the active control group. There were no deaths reported during the study.

Incidences of each event were similar for both groups, except for knee joint effusion, which was reported by 9 patients in the active control group and one patient in the EUFLEXXA® treatment group. A total of 160 patients received 478 injections of EUFLEXXA®. There were 27 reported adverse

events considered to be related to EUFLEXXA® injections: arthralgia – 11 (6.9%); back pain – 1 (0.63%); blood pressure increase – 3 (1.88%); joint effusion – 1 (0.63%); joint swelling – 3 (1.88%); nausea – 1 (0.63%); paresthesia – 2 (1.25%); feeling of sickness of injection – 3 (1.88%); skin irritation – 1 (0.63%); tenderness in study knee – 1 (0.63%). Four adverse events were reported for the EUFLEXXA® group that the relationship to treatment was considered to be unknown: fatigue – 3 (1.88%); nausea – 1 (0.63%).

### Single Center Study

In a single-center, single-blinded, placebo controlled, prospective, two parallel treatment arm clinical trial a total of 49 (25 EUFLEXXA®, 24 placebo) patients were randomized into two treatment groups in a ratio of 1:1 EUFLEXXA® or placebo. A total of 65 adverse events were reported by 17 (68%) of the patients in the EUFLEXXA® group and 15 (63%) in the placebo group. Of the 65 total events reported, 20 were regarded as treatment related. Knee pain, hypokinesia of the knee, knee swelling, and rash were considered to be treatment related adverse events.

### DETAILED DEVICE DESCRIPTION

Each syringe of EUFLEXXA® contains:

Sodium hyaluronate	20 mg
Sodium chloride	17 mg
Disodium hydrogen phosphate dodecahydrate	1.12 mg
Sodium dihydrogen phosphate dihydrate	0.1 mg
Water for injection	q.s.

### HOW SUPPLIED

EUFLEXXA® is supplied in 2.25 ml nominal volume, disposable, pre-filled glass syringes containing 2 ml of EUFLEXXA®. Only the contents of the syringe are sterile. EUFLEXXA® is nonpyrogenic. 3 disposable syringes per carton.

This product is latex-free.

### DIRECTIONS FOR USE

- Do not use EUFLEXXA® if the package is open or damaged. Store in the original package below 77°F (25°C). Do not freeze. Protect from light.
- EUFLEXXA® is administered by intra-articular injection into the knee synovial capsule using strict aseptic injection procedures. The full content of the syringe is injected into the affected knee at weekly intervals for 3 weeks, for a total of 3 injections.

Toll free number for providers and patients to call with questions: 1-(888)-FERRING (1-(888)-337-7464).

### MANUFACTURED FOR:

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References: 1. IMS data. February 2008. 2. Kirchner M, Marshall D. A double-blind randomized controlled trial comparing alternate forms of high molecular weight hyaluronan for the treatment of osteoarthritis of the knee. *Osteoarthritis Cartilage*. 2006;14:154-162.