MEDCO FORUM®

PRESENTING INNOVATIVE PRODUCTS & SERVICES TO HEALTHCARE PROFESSIONALS

VOLUME 15 NUMBER 5 MARCH 2008

REPRINT

ULTRA PURE EUFLEXXA™ (1% SODIUM HYALURONATE) VISCOSUPPLEMENTATION THERAPY FOR OSTEOARTHRITIS OF THE KNEE

Give your patients more than pain relief—improve their quality of life

While it is easily understood how osteoarthritis (OA) negatively impacts an individual's ability to function physically, the adverse effects on a patient's psychological well-being are not as apparent and often overlooked. The inability to take care of oneself or participate in social or leisure activities due to the pain of OA may lead to depression or other comorbidities.[1] Accordingly, it is crucial to examine patients' views of treatment and its impact on their lives to effectively manage their condition.[1]

One recent study looked at patients' perceptions of the degree of relief obtained with **EUFLEXXA**™ (1% sodium hyaluronate), a viscosupplementation therapy from **Ferring Pharmaceuticals (St. Prex, Switzerland)**. FDA-approved EUFLEXXA is the first and only non-avian-derived hyaluronic acid (HA) available in the U.S. for the treatment of pain caused by OA of the knee. Information for the study was collected from patients through three surveys (at baseline, three months and six months) via an automated interactive voice response system. One hundred sixty-one patients completed the three surveys. Survey content included the WOMAC Osteoarthritis Index sub-scale for pain, as well as demographic and clinical information. Results revealed that patients reported a statistically significant reduction in knee pain following treatment with EULFEXXA, with the mean WOMAC score of 9.4 (range of 0 to 20) at baseline, decreasing to 6.2 after a mean of 98 days ($p<0.01$) and sustaining at 6.2 out to a mean of 175 days ($p<0.01$ vs. baseline).[1] Differences in the distributions of patients by pain severity before and after use of EULFEXXA were statistically significant ($p<0.05$) for each individual WOMAC pain measure (i.e., going up or down stairs, walking on a flat surface, at night in bed, sitting or lying down and standing upright).[1] For each of these pain measurements, the number of patients reporting mild or no pain increased after both three and six months with EUFLEXXA as compared to baseline.[1] The authors concluded that patients perceived EUFLEXXA as effective for reducing the severity of pain associated with OA, even as far out as six months.[1] Furthermore, they believe that subjective data interpreted alongside objective clinical information would be useful in optimizing patient care.[1]

Erol Onel, MD, Director of Medical Affairs, Orthopaedics, at Ferring Pharmaceuticals, an author of the study, noted that another interesting aspect of the study revealed patients' perceptions of how pain interfered with activities of daily living and social and leisure time. "The

FDA-approved EUFLEXXA™ (1% sodium hyaluronate), a viscosupplementation therapy from Ferring Pharmaceuticals (St. Prex, Switzerland), is the first and only non-avian-derived HA approved in the U.S. for the treatment of pain caused by OA of the knee.

mean baseline for pain interference with activities of daily living was 5.8 (range of 0 to 10; "0" does not interfere at all to "10" interferes very much). This number went down to 3.7 at three months, remaining at a low level of 3.9 at six months. Furthermore, the mean baseline for pain interfering with social and leisure time was 5.6. Three months later this number went down to 3.6 and, at six months, stayed down at 3.7. While the three- and six-month numbers are statistically significant from the baseline, they are not statistically significant from each other." Dr. Onel points out that "this is one of the first studies that has actually looked at how pain from OA affects activities of daily living and social and leisure time. Now, we have some data confirming that patients *feel* the benefits of EUFLEXXA for a full 26 weeks. It's quite satisfying to see how EUFLEXXA brings relief to patients so they can once again do things independently and return to the social and leisure activities that they enjoy."

EUFLEXXA is indicated in patients who have failed to respond adequately to conservative non-pharmacologic therapy and simple analgesics. EUFLEXXA is a very highly purified product bioengineered from outside bacterial cells and has a high molecular weight and straight-chain structure most similar to the HA found in healthy human synovial fluid. EUFLEXXA is also free of chemical cross-linking, which minimizes the risk of related reactions.[2,3,4,5,6,7] A course of treatment with EUFLEXXA consists of three injections, one each week for three weeks, whereas other similar products require a series of up to five injections to receive the significant benefit. "This is just one of the advantages of EUFLEXXA," notes Mark R. Rogers, MD, an orthopedic surgeon with West Houston Orthopedic & Sports Medicine Center (Houston, TX). "I have found no adverse drug interactions and few or no side effects. This lack of negative side effects can be directly attributed to the purity of EUFLEXXA." Cumulative data has confirmed the clinical safety and efficacy of this treatment modality and suggests that it may be effective in symptomatic relief of patients with OA.[8]

Dr. Rogers previously began patient treatment for OA with oral anti-inflammatory medications, followed by cortisone injection if the oral medication did not result in an improvement of symptoms. "In the last year or two, however, I'm finding myself more inclined to use EUFLEXXA as a first-line treatment for mild to moderate osteoarthritis. I believe it is a very beneficial treatment and should become more of a first-line—and certainly second-line—treatment for osteoarthritis in the knee." Dr. Rogers has found that 80 to 85 percent of his patients with mild to moderate OA have enjoyed significant relief from EUFLEXXA. "While there may not be total relief from pain, they have enough relief where they only occasionally have to use a simple, over-the-counter analgesic to help, as opposed to suffering every day." Dr. Rogers notes that by extension, this relief from pain has helped patients realize an improvement in their quality of life. "Many patients are able to get up out of a chair much more easily. They have also reported the loss of morning stiffness as well as greatly reduced pain at night."

Osteoarthritis, the most prevalent form of arthritis and one of the most common diseases affecting humans, is characterized by progressive damage to joint cartilage and changes to structures around the joint. It causes pain (often severe) and limited range of motion in the affected joint. More than 20 million Americans have symptomatic OA and, as our population ages, this number will continue to rise.[9,10] Studies have shown that such musculoskeletal conditions are associated with substantial direct and indirect costs, exceeding more than $200 billion dollars annually.[11,12,13]

To Learn More

For more information, please visit www.EUFLEXXA.com, or call 1-888-337-7464.

euflexxa™
HIGHLY PURIFIED HYALURONAN

References:

1. Onel E, Kemey DL, Rogers MR, Patients' Perceptions of the effect of Hyaluronic Acid (Euflexxa) on Osteoarthritis-Induced Knee Pain, Presented at the 2007 World Congress on Osteoarthritis, December 2007, Fort Lauderdale, FL.
2. Schiavinato A, Finesso M, *et al.* Comparison of the effects of intra-articular injections of Hyaluronan and its chemically cross-linked derivative (Hylan G-F20) in normal rabbit knee joints. *Clin Exp Rheumatol* 2002;20:445-454.
3. Goomer RS, Leslie K, *et al.* Native hyaluronan produces less hypersensitivity than cross-linked hyaluronan. *Clin Orthop Relat Res* 2005;239-245.
4. Leopold SS, Warme WJ, *et al.* Increased frequency of acute local reaction to intra-articular hylan GF-20 (synvisc) in patients receiving more than one course of treatment. *J Bone Joint Surg Am* 2002;84-A:1619-1623.
5. Puttick MP, Wade JP, *et al.* Acute local reactions after intraarticular hylan for osteoarthritis of the knee. *J Rheumatol* 1995;22:1311-1314.
6. Pullman-Mooar S, Mooar P, *et al.* Are there distinctive inflammatory flares after hylan g-f 20 intraarticular injections? *J Rheumatol* 2002;29:2611-2614.
7. Chen AL, Desai P, *et al.* Granulomatous inflammation after Hylan G-F 20 viscosupplementation of the knee: a report of six cases. *J Bone Joint Surg Am* 2002;84-A:1142-1147.
8. Brockmeier, SF, Shaffer, BS. Viscosupplementation Therapy for Osteoarthritis, *Sports Med Arthrosc Rev* 2006;14:155-162.
9. Lawrence RC, Helmick CG, et al. Estimates of the prevalence of arthritis and selected musculosketal disorders in the United States. *Arthritis Rheum* 1998;41:778-99.
10. Oliveria SA, Felson CT, *et al.* Incidence of symptomatic hand, hip and knee osteoarthritis among patients in a health maintenance organization. *Arthritis Rheum* 1995;38: 1134-41.
11. Onel E, Kemey DL, Rogers MR, Patients' Perceptions of the effect of Hyaluronic Acid (Euflexxa) on Osteoarthritis-Induced Knee Pain, Presented at the 2007 World Congress on Osteoarthritis, December 2007, Fort Lauderdale, FL.
12. Gabriel SE, Crowson CS, *et al.* Direct medical costs unique to people with arthritis. *J Rheumatol.* 1997;24: 719-25.
13. Gabriel, SE Crowson CS, *et al.* Indirect and nonmedical costs among people with rheumatoid arthritis and osteoarthritis compared with nonarthritic controls. *J Rheumatol.* 1997;24:43-8.