

## POLICY &amp; PRACTICE

**TNF- $\alpha$  Inhibitors Are Top Choice**

Tumor necrosis factor- $\alpha$  inhibitors are likely to continue to dominate the rheumatoid arthritis marketplace, according to the results of a survey of 102 rheumatologists conducted by Decision Resources. Almost all reported prescribing TNF- $\alpha$  inhibitors as a first-line biologic therapy. Most reported trying two or more TNF- $\alpha$  inhibitors before trying a treatment with a different mechanism of action. Physicians said they preferred TNF- $\alpha$  inhibitors because they were familiar with the drugs and these drugs were effective in treating

RA. The class of drugs is expected to get a boost with the upcoming launch of two new drugs—certolizumab pegol (Cimzia) and golimumab, according to Decision Resources. “Most rheumatologists expect the dominance of TNF- $\alpha$  inhibitors to continue, and possibly expand, over the next 2 years,” Decision Resources director Cindy Mundy, Ph.D., said in a statement. “Following the launches of Cimzia and golimumab, nearly half of surveyed rheumatologists expect to prescribe three or more TNF- $\alpha$  inhibitors before moving to a different class of agents.”

**New Leadership at NIAMS**

Dr. Robert H. Carter, a leading researcher and rheumatologist, will become the new deputy director of the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), part of the National Institutes of Health, this fall. Dr. Carter is a former director of the division of clinical immunology and rheumatology at the University of Alabama at Birmingham and is the principal investigator of the university's NIAMS-supported Rheumatic Disease Core Center. In his new role, Dr. Carter will assist in developing the NIAMS portfolio of research from basic science to translational re-

search. “His stellar credentials as a scientist and his broad experience in NIH extramural activities will contribute to NIAMS' long history of excellence in biomedical research,” Dr. Stephen Katz, NIAMS director, said in a statement.

**Health Searches Level Off**

The number of adults going online for health information has plateaued or declined, according to a Harris Interactive poll. According to the pollster, a total of 150 million people—66% of all adults and 81% of those who have online access—said they obtained health information from the Internet in 2008. That represents a slight drop from 2007, when the poll found that 160 million people reported obtaining health information online. The researchers who conducted the poll noted that the slight differences from 2007 to 2008 are within the possible sampling error. But they pointed out that, in contrast to other years, it appears that there has been no increase in the total number of people with Internet access or in the number of people searching for health information—those the poll calls “cybercondriacs”—indicating that a plateau or even a slight decline was underway. Just under half of cybercondriacs said that they had discussed the information they obtained online with their doctors, and 49% had gone online to look for information as a result of discussions with their doctors, the survey found.

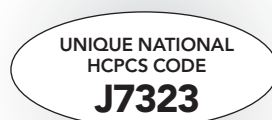
**Home Drug Errors Rise**

A shift in the number of medications being taken outside of the hospital has correlated with a sharp increase in the number of fatal medication errors in the home, researchers reported in the Archives of Internal Medicine. In the study, sociologists at the University of California, San Diego, found a 3,196% increase in fatal domestic medication errors involving alcohol and/or street drugs, and a 564% increase in domestic medication fatalities not involving alcohol and/or street drugs. The study examined nearly 50 million U.S. death certificates from 1983 to 2004, and focused on the 200,000 deaths involving medication errors. The authors said they noted that it may be possible to reduce fatal medication errors by focusing education efforts on domestic settings in addition to clinical settings.

**GAO: Part D Problems Continue**

Almost 3 years after the Medicare Part D drug program went into effect, the Centers for Medicare and Medicaid Services still faces significant and continuing problems resolving beneficiaries' complaints and grievances, a Government Accountability Office report found. GAO said that there have been 630,000 complaints filed with the CMS against drug plans since Part D went into effect, most involving problems of enrollment and disenrollment. Although GAO found that the number of complaints, and the time to resolve them, had declined in the first 2 years of the program, it also found that “a substantial proportion of the most critical complaints—those filed when beneficiaries were at risk of exhausting their medications—were not resolved within CMS's applicable time frames.”

—Mary Ellen Schneider

**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:**

FERRING PHARMACEUTICALS INC.  
PARSIPPANY, NJ 07054

**MANUFACTURED BY:**

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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.