

NewsAlert from AdverseEvents, Inc.

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SERIOUS SIDE EFFECT RISKS FROM OSTEOPOROSIS MEDICATIONS:

Important Differences Between the Top Selling Drugs

HEALDSBURG, CA (September 8, 2011) - AdverseEvents, Inc. utilized RxFilter™, a proprietary data aggregation and refinement process, to identify important differences in side effect risks *between* the four most popular bisphosphonate drugs that are widely used to treat osteoporosis in over 10 million patients worldwide. Of the twenty separate adverse event categories reviewed, Reclast (injectable) (manufactured by Novartis) had the highest percent risk in fourteen categories, followed by the oral medication Fosamax (manufactured by Merck) with six. Fosamax (alendronate), which is the number one selling drug in the class, appeared to be consistently linked to higher adverse event risks than the other two oral bisphosphonates (Actonel and Boniva), neither of which showed the highest risk in any of the twenty adverse event categories analyzed. No other analysis of this scope has been conducted regarding post-marketing adverse events linked to the bisphosphonates. Prescribing doctors and patients must review this new information in order to determine their own risk-benefit scenario when considering this class of drug treatment.

In order to address the growing concern over the increasing rate of severe side effects [atypical femur fractures (unusual broken thigh bone) and osteonecrosis of the jaw (jawbone death)] suffered by osteoporosis patients, the FDA has called a meeting on September 9, 2011 to “discuss the benefits and risks of long-term bisphosphonate use for the treatment and prevention of osteoporosis (thinning and weakening of bones that increases the chance of having a broken bone) that may be associated with the long-term use of bisphosphonates”.

The incidence of serious adverse events linked to widely prescribed osteoporosis drugs has been steadily increasing. Regulatory bodies have been unable to provide data that is easy to retrieve, use, and analyze. With the launch of AEI’s RxFilter™ process, however, once obscure data in the FDA’s AERS (Adverse Events Reporting System) is now available to review and act upon, providing an opportunity to identify health risks faster than ever before.

Osteoporosis is a widespread condition associated with low bone density and mass, resulting in increased risks of bone fractures. Drugs from the class known as bisphosphonates have been used to decrease fracture rates in at-risk patients. The most popular bisphosphonates are Fosamax (alendronate), Actonel (risedronate), Reclast (zoledronic acid), and Boniva (ibandronate). These drugs are widely prescribed to patients with osteoporosis due to their significant efficacy record. However, due to the fact that these drugs stay active in patients for years after dosing, many of the adverse events associated with these compounds may not have been properly captured in their time-constrained clinical trial testing phases. Continued detailed surveillance of post-marketing adverse events associated with FDA-approved bisphosphonates is of vital importance.

Methodology

RxFilter, a proprietary 17-step data refinement process developed by AdverseEvents, Inc., was used to perform a comprehensive analysis of bisphosphonate-linked adverse event case reports found in the FDA’s AERS database. Drugs were included that had cases reported to the FDA in the time period of January 1, 2004 to March 31, 2011. The bisphosphonate drugs examined were: Fosamax, Actonel, Reclast, and Boniva, and included generic equivalents and foreign designations. A detailed search of the AERS database, and accompanying case report forms, was performed in order to identify potentially important medication-related adverse events, with special emphasis placed on current FDA concerns such as atypical femur fractures, osteonecrosis of the jaw, jaw fractures, and kidney failure.

Conclusion

Post-approval adverse event analysis using the RxFilter process in large, post drug approval, consumer populations indicates that serious side effects from bisphosphonates may be more common than currently appreciated, and that drugs *within* the class show varied risk rates. Femur and jaw fractures, bone death, kidney failure, bone infections, and various muscle and

tendon disorders are serious adverse events associated with the top selling bisphosphonate class of drugs used to treat osteoporosis (Fosamax, Actonel, Reclast, and Boniva). Such side effects appear to be on the rise in consumer populations likely because many do not fully manifest until years after bisphosphonate treatment begins. Because of this significant latency, it is likely that these adverse events were not properly evaluated during time-constrained clinical testing phases associated with each drug. Prospective studies, however, are needed to establish the exact incidence rates for these adverse events. This analysis warrants the attention of all healthcare providers and patients associated with bisphosphonate and other bone anti-resorptive medications.

About AdverseEvents, Inc.

AdverseEvents, Inc. (AEI) is the first service provider to deliver accurate, real-time information on adverse drug events reported to the FDA. AEI utilizes a unique data sourcing method called RxFilter™, a proprietary 17-step data refinement process that standardizes and normalizes the data from the FDA's Adverse Event Reporting System (AERS) into a user-friendly, fully searchable, database of over 4,000 approved medications. Over 500,000 medication adverse events are reported yearly to the FDA, estimated to be only 10% of all actual adverse events. As a leading resource for the pharmaceutical industry, AEI supports companies with competitive intelligence and data to inform drug marketing decisions and business development strategies. With AEI, the healthcare industry is able to quantify the benefit-risk assessments of FDA approved drugs to fully understand the scope of safety issues, based on accurate rates of side effects from such medications. For more information about Adverse Events, please visit www.adverseevents.com.

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