Fosamax FDA Warning

Fosamax is a prescription drug used to treat osteoporosis. It is a member of a class of drugs called bisphosphonates. Since the approval of Fosamax in 1995, a number of users have reported adverse effects from using the drug. Fosamax side effects include femur fracture, osteonecrosis of the jaw, esophageal cancer, and severe musculoskeletal pain.

The high number of adverse event reports has caused the U.S. Food and Drug Administration (FDA) to release a series of Fosamax FDA warnings regarding the safety of the drug and other bisphosphonates. In many cases, the FDA has required that the drug's safety label include warnings of these risks. As a result, a number of Fosamax patients have filed lawsuits against Merck, the manufacturer of the drug.

Fosamax Femur Fracture

In 2010, the FDA released a Drug Safety Communication warning the public of the potential increased risk of sustaining fractures in the femur, or thigh bone, in bisphosphonate patients. These atypical fractures include diaphyseal and subtrochanteric fractures. Diaphyseal fractures occur along the long shaft of the bone. Subtrochanteric fractures occur immediately below the femur's lesser trochanter, or just below the hip joint.

Following the Fosamax FDA warning, manufacturing companies were required to add femur fracture information to bisphosphonate safety labels. However, the warning did not affect bisphosphonate drugs used exclusively for treating Paget's disease or cancer-induced high blood calcium.

Fosamax Severe Pain

In 2008, the FDA released an alert regarding bisphosphonates such as Fosamax, Actonel, Reclast, and Boniva. The warning noted to consumers that many bisphosphonate users suffered severe bone, muscle, or joint pain during treatment with the drugs. In many cases, patients reported pain that was so debilitating that it interfered with their normal, daily activities.

This musculoskeletal pain occurred within users after days, months, and years of beginning bisphosphonate treatment. Some patients experienced complete pain relief after taking the drug. However, many reported slow or incomplete relief. Many medical professionals dismissed this pain as a symptom of osteoporosis. The announcement urged medical professionals to consider

temporarily or permanently discontinuing bisphosphonate treatment in patients experiencing pain.

Fosamax Osteonecrosis

The FDA has required the Fosamax label to include warnings of a condition called osteonecrosis of the jaw. It is also known as Dead Jaw Syndrome. Osteonecrosis of the jaw can lead to the complete collapse of the jawbone. It typically begins with a minor oral wound, such as one from routine dental work. The wound can then become infected and interfere with blood flow to the jaw. As a result, the jawbone can become so brittle that it eventually collapses.

Fosamax Hyocalcemia

The Fosamax warning also indicates a potential increased risk of hypocalcemia, or low blood calcium levels. In patients with preexisting hypocalcemia, Fosamax may worsen the condition. Symptoms of hypocalcemia include twitches, spasms, or cramps in the patient's muscles. The patient may also experience tingling or numbness in the toes, fingers, or around the mouth.

Fosamax Atrial Fibrillation

A 2007 Fosamax FDA warning discussed concerns regarding a potential risk for atrial fibrillation in patients taking Fosamax and other bisphosphonates. This announcement came after *The New England Journal of Medicine* featured an article describing increased atrial fibrillation rates in bisphosphonate patients who took the drug for osteoporosis treatment.

Fosamax Esophageal Cancer

In 2011, the FDA issued a Drug Safety Communication discussing the potential risks of bisphosphonates and esophageal cancer. The announcement stated that there was conflicting evidence to whether or not Fosamax and other bisphosphonates cause cancer of the esophagus. One of the major studies reviewed by the FDA indicated no increased risk. However, another study examined patients who took bisphosphonates for more than three years. These patients exhibited double the risk of developing esophageal cancer.

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