

## WEST VALLEY PERIODONTICS

### **Informed Consent Relating to Risks Associated with Oral Bisphosphonate Use**

The following provides you with some additional information about dental treatment for patients taking oral bisphosphonates. Because you are taking a type of drug called a bisphosphonate, you may be at a small risk for developing osteonecrosis of the jaw and certain dental treatments may increase that risk. You should understand that the risk for developing this condition is very small.

#### **What are bisphosphonates?**

Bone is a living tissue with living cells and a blood supply. About 1% of your bone mass dies off and is replaced with new bone every day. Bisphosphonates reduce this bone cell turnover. Intravenous/injected bisphosphonates (such as Zometa, Aredia and the injectable form of Boniva) are primarily used in some type of cancer patients, reducing severe bone pain and even death. Oral (pill form) bisphosphonates, such as Fosamax, Actonel and the oral form of Boniva, are heavily advertised and commonly prescribed for osteoporosis prevention. (Example—in 2005 there were 22 million prescriptions in the US for Fosamax valued at 3 billion dollars.) It is estimated that 50% of intravenously/injected administered bisphosphonate is bio-available and 50% excreted; the oral form is only 1% bioavailable and 99% excreted. So intravenous administration is 50 times more potent. Once bisphosphonates are absorbed in bone, they remain there for a long time. Most drugs have a half-life (the time it takes for the body to remove half of a bioavailable drug) measured in hours. Bisphosphonates become incorporated in bone and their half-life is 10 years, regardless of the method of administration.

#### **What is osteonecrosis of the jaw?**

Osteonecrosis means death of bone, which can occur from the loss of the blood supply or by a problem with the bone's ability to regrow. Osteonecrosis of the jawbones has been associated with head and neck cancer radiation treatment (not routine x-rays). This form has been treatable with hyperbaric oxygen therapy.

Recently there have been cases of osteonecrosis of the jawbone in individuals taking bisphosphonates. In 2004 Ruggiero, et al first reported this in 63 patients they saw over 3 years with jawbone necrosis. 89% were taking intravenous bisphosphonates for cancer treatments, and 11% were taking oral bisphosphonates for treatment of osteoporosis, osteopenia, or Paget's disease of bone. ¼ of these cases involved no recent dental treatment; they occurred spontaneously. ¾ of cases occurred after dental treatment or from denture sore spots. It is not known whether dental treatment caused the osteonecrosis of the jawbone, or exacerbated a pre-existing, sub-clinical osteonecrosis that did not yet become full blown. Since the half-life is 10 years, stopping these drugs does not make the osteonecrosis get better.

#### **What is the risk for developing bisphosphonate osteonecrosis of the jaw (BONJ)?**

As of the beginning of 2006, there are about 100 cases worldwide of BONJ related to oral bisphosphonates. Your risk for developing osteonecrosis of the jaw (BONJ) from using oral bisphosphonates is estimated at less than one

per 140,000 person-years of exposure to the drugs Fosamax, Actonel or oral Boniva. If it does occur, it may be a serious condition with no known treatment, so you should be aware of this rare complication. At this time, there is no way to determine who will develop BONJ. However, the condition is very rare with oral bisphosphonates. It is important for you to understand that other factors may play a role in the development of osteonecrosis, such as other medications you are taking and health problems that you may have.

BONJ only occurs in jaw bones (upper and lower jaws....maxilla and mandible). It does not occur in other bones.

**Should I stop taking oral bisphosphonate?**

The benefits of reducing hip fractures and other complications associated with osteoporosis can be very important. Your dentist cannot advise you about these benefits. You should talk with your physician if you have any questions.

**What are the signs and symptoms of osteonecrosis of the jaw?**

You should tell your dentist immediately if you have any of the following symptoms, now or in the months following treatment:

- feeling of numbness,
- heaviness or other sensations in your jaw pain in your jaw
- swelling of your jaw
- loose teeth
- drainage
- exposed bone

It needs to be mentioned that many of the above are normal postoperative occurrences that go away in a short period of time, or may be strictly a “routine” dental problem

Any patient that would, by some chance, develop BONJ would be referred for treatment/management to an oral surgeon or oral medicine specialist versed in BONJ. Dr. Bohra has not had a case of BONJ and thus has no personal experience in its management.

**Risks associated with not having the procedure.**

Your risk for developing osteonecrosis of the jaw is very small. You may also be at increased risk for developing other health problems if a dental disease is not treated. Active periodontitis is also associated with a significant increase in the risk of heart attacks, stroke and pregnancy complications and is well documented in the medical literature. In 2005, Marx reported the most common dental problem in patients with BONJ is existing active periodontitis (active gum disease).

Your dentist(s) can discuss alternative treatments, other risks associated with various treatment options, and the risk of no treatment. You should also consult with your treating physician about any medical health benefits and health risks associated with bisphosphonates.

Name\_\_\_\_\_

Signature\_\_\_\_\_

Date\_\_\_\_\_