



Informed Consent for Patients Taking Bisphosphonate and Prolia Drugs

By signing this consent, you are indicating that you and your periodontist have thoroughly discussed the risks, benefits and alternatives for the treatment you will be given and that you have understood that discussion.

Because you are taking a type of drug called a bisphosphonate, you may be at risk for developing osteonecrosis of the jaw and certain dental treatment may increase that risk. You should understand that the risk for developing this condition is very small.

Bisphosphonates are given intravenously in cancer treatment and have brand names such as Bonafos, Aredia, Skelide and Zometa. They are also used for osteoporosis treatment and can be given either as a subcutaneous injection or as a pill and have brand names such as Prolia, Fosamax, Didronel, Actonel and Boniva. These drugs stay in the body and can cause side effects many years after they were taken.

What is osteonecrosis of the jaw?

Osteonecrosis means death of the bone which can occur from the loss of the blood supply or by a problem with the bones ability to regrow. Very rarely, osteonecrosis of the jawbone has occurred in individuals taking oral bisphosphonates for treatment of osteoporosis or Paget's disease of the bone. Dental treatment that involves bone can be a risk factor.

What is the risk for developing osteonecrosis of the jaw?

Your risk for developing osteonecrosis of the jaw, from using oral bisphosphonates, is very small (estimated at less than one person per 100,000 person-years of exposure to the drugs Fosamax, Actonel, or Boniva); but, if it does occur, it may be a serious condition with no known treatment, so you should be aware of this complication. At this time, there is no way to determine who will develop the disease. However, the condition is rare and has just recently been associated with the use of 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, health problems you may have, and smoking.

Should I stop taking the oral bisphosphonates?

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. Also, it has not been definitely shown that stopping the use of the drug will decrease your risk for developing osteonecrosis.

What are the risks associated with dental procedures?

Although the risk is low with any procedure, procedures involving the bone such as tooth extractions, implants, and periodontal surgery add to the risk. Even ill-fitting dentures can be a factor.

How can I decrease my risk of developing osteonecrosis of the jaw?

Talk to your dentist about oral hygiene and diet, because maintaining good oral hygiene and a low-cavity causing diet is the best way to prevent oral diseases. Have your dentist take appropriate x-rays. Have a thorough dental exam and complete recommended care.

What are 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

What other choices do I have if I do not have the procedure?

Your treatment options depend on the oral health condition that you have. Your dentist will be able to discuss treatment options with you. The risk of not having treatment may outweigh the risk of having treatment.

Risks associated with not having the procedure.

You may be at increased risk for developing osteonecrosis or other health problems if a dental disease is not treated. Your dentist will be able to discuss other risks associated with various treatment options, and the risk of no treatment, even temporarily. You should also consult with your treating physician about any health risks.

Patient Name/Signature: _____ Date: _____