

Obtaining Informed Consent Relating to Risks Associated with Oral Bisphosphonate Use

What is the purpose of this document?

A consent form is simply a document to confirm that a patient has knowingly consented to a particular treatment. The key is the discussion between the dentist and patient during which the treatment, its risks and benefits and alternatives, are all discussed. An informed consent form is evidence this discussion took place. It should be signed and dated by the patient. One copy should be given to the patient and another copy should be retained in the patient's file. The following document may be used during that discussion to help guide it.

The requirements for informed consent forms may vary from one jurisdiction to another. You should consult with an attorney to develop a form which will be effective in your state. The following document contains only a general discussion of issues surrounding treating patients taking oral bisphosphonates. It does not contain the specific information likely required to be in an informed consent form. It is designed, however, to provide general information to your patient and to guide you in fully and clearly explaining risks, benefits and treatment alternatives to your patient.

What is an informed consent form?

Your dentist wants you to understand the treatment you are considering. To do so, you need to understand the risks associated with that treatment, as well as the benefits of the treatment. Your dentist also wants you to understand the alternatives available to you, from no treatment to other treatment options. This is also an ideal time to have your dentist answer any questions you may have. By signing a consent to treatment form, you are indicating that you and your dentist have thoroughly discussed the risks, benefits and alternatives for the treatment you will be given and that you have understood that discussion.

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 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 is osteonecrosis of the jaw?

Bone is a living tissue with living cells and a blood supply. 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. Very rarely, osteonecrosis of the jawbone has occurred in individuals taking oral bisphosphonates for treatment of osteoporosis or Paget's disease of bone. Dental treatments that involve the bone can make the condition worse.

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 and health problems that you may have.

Should I stop taking the 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. Also, it has not been shown that stopping 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, it is higher with procedures involving the bone and associated tissues, such as tooth extractions. Your dentist will be able to tell you if the procedure will involve these tissues.

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

Talk to your dentist about oral hygiene, because maintaining good oral hygiene is the best way to prevent oral diseases that may require dental surgery.

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

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.

Risks associated with not having the procedure.

Your risk for developing osteonecrosis of the jaw is very small. You may be at increased risk for developing other health problems if a dental disease is not treated. Your dentist will be able to discuss alternative treatments, 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.