SIGMA CANADIAN MENOPAUSE SOCIETY

BONE ANABOLIC THERAPY:

Frequently Asked Questions

sigma
Canadian
Menopause Society

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BONE ANABOLIC THERAPY: *FAQ*

WHAT IS FORTEO AND HOW DOES IT WORK ON THE BONE?

Forteo, also known as teriparatide, is a small part of the natural parathyroid hormone (PTH) molecule. PTH is the hormone responsible for maintaining blood calcium as well as bone calcium and bone strength. PTH is normally produced in the parathyroid glands of the neck in amounts required to keep blood calcium levels steady and normal. If the blood levels of PTH are increased by an over-activity of the parathyroid glands, the blood calcium level will rise and bone calcium, often measured by bone density testing, will decline (a condition called hyperparathyroidism).

Forteo injections give the body a pulse of PTH action, stimulating the bone forming cells, called osteoblasts, to build new bone within the skeleton. Although the bone removal cells (osteoclasts) are also briefly stimulated as well, this effect is much less pronounced, so the overall effect is a true increase in bone tissue. The pulse of Forteo remains active for only 2-4 hours, after which time the medication has been broken down by the body and is no longer active. This daily stimulation of the bone forming cells leads gradually to the building up of new bone. This benefits bone strength and reduces fracture risk in patients who take Forteo.

WHAT IS THE BENEFIT OF TAKING FORTEO OVER OTHER DRUGS FOR OSTEOPOROSIS?

All other osteoporosis medications, apart from Forteo, can prevent the breakdown of existing bone by osteoclasts. As a group, these "antiresorptive" therapies are effective in preserving existing bone but not producing new bone. Such medications include Fosamax (alendronate), Actonel (risedronate), Didrocal (etidronate), Aclasta (zoledronate), Prolia (denosumab), estrogen, Evista (raloxifene), Miacalcin (calcitonin), and others. The reason bone density might increase on these treatments is due to the aging of bone which allows more calcium to deposit into the bone tissue. Although the actual amount of bone is not increased, there is more calcium deposited into the existing bone, making the bone harder and more resistant to fracture. This is one of the reasons why patients on these therapies suffer fewer fractures.

With Forteo, the bone forming cells are stimulated to produce new bone, improving not just the amount of calcium in bone but actually encouraging new bone formation and effectively replacing the bone structure which might have been lost with age or disease. This can be of both short and long-term benefit in reducing the risk of fracture.

CAN FORTEO BE COMBINED WITH OTHER OSTEOPOROSIS DRUGS? CAN FORTEO BE USED AS THE FIRST OSTEOPOROSIS TREATMENT?

Usually your doctor will recommend either single therapy with a bisphosphonate drug such as Fosamax or Actonel or single therapy with Forteo. With severe osteoporosis (often described as osteoporosis with existing fragility fracture), starting with Forteo first, before antiresorptive therapies, may be the optimal course of treatment. If there is insufficient response to bisphosphonate or other antiresorptive therapy, your doctor may decide to switch to Forteo as bone building therapy. Forteo is usually given on its own for 2 years, followed by a return to an antiresorptive. The prior use of some antiresorptive therapies such as Fosamax and Actonel may blunt or slow the bone building effects of Forteo.

WHY DID THE BMD NOT GO UP AFTER A YEAR ON FORTEO? SHOULD I STOP THE DRUG?

The bone density (DXA) test is a measurement of the calcium in the bone. It is only an indirect measurement of the amount of bone present. With Forteo, old bone containing a lot of calcium is removed and replaced with new bone containing less calcium (initially). Because of this, the bone density may initially go down a little and then increase later when calcium has deposited into the newly formed bone. If we used research techniques to view the bone architecture or structure, we could see the new bone which has been formed. Such bone imaging tests are not yet available clinically.

Since the bone responds only very slowly to treatments (and different individuals may have differing responses), you should be patient and continue Forteo therapy for the full course that your doctor will recommend, usually 2 years.

ARE THERE WAYS OF DETERMINING IF THE DRUG IS WORKING OTHER THAN BONE DENSITY TESTING?

Bone density (or DXA) testing is the most commonly-available test to monitor osteoporosis therapies. With most bone treatments, bone density either remains the same or increases gradually over time. In order to detect a rise in bone density, it will often take a year or two of treatment. Bone density tests before this may be difficult to interpret due to the limitation of precision of DXA scans.

In order to see an earlier sign of bone formation, there is a blood test called P1NP. This test is not available in all parts of the country. P1NP is an indicator of bone turnover which reflects the action of the osteoblasts (the cells that produce new bone). If tested before starting Forteo and then again after 3 months on therapy, it will be seen in most cases to rise significantly. This can be reassuring to you and your doctor that new bone formation is being stimulated and that the desired reduction in fracture risk is likely to occur.

FORTEO IS VERY EXPENSIVE. IS IT WORTH IT? WHAT IF MY DOCTOR RECOMMENDS TREATMENT BUT I CANNOT AFFORD IT?

Although the daily cost of medication is important to consider, we must also consider the benefits of therapy. Forteo is the only bone building therapy available. Forteo has unique effects on bone which are quite different from any of the other osteoporosis therapies. Forteo adds new bone tissue, improving the architecture of bone and effectively returning the bone to what it might have been like many years prior to starting therapy. If fragility fractures are continuing to occur while on antiresorptive therapy (such as Didrocal, Fosamax or Actonel), it might indicate that preserving the existing bone is not sufficient and that a different strategy should be taken. Forteo, as the only bone building therapy, may be the best option in such cases. Rebuilding bone for 2 years, followed by one of the other osteoporosis therapies to preserve that new bone, may be your most effective strategy. The investment in Forteo over 2 years with appropriate ongoing treatment might, therefore, pay off dividends in fracture risk reduction over all of the remaining years of your life.

Forteo is not covered by all of the Provincial medication formularies. It is covered by most of the extended medical benefit plans. If Forteo is recommended but you cannot afford the cost, the Forteo Customer Care Program may be able to help you. Through this Program, the Reimbursement Experts can explore with you potential opportunities to obtain economic assistance to help you to access Forteo.

WHAT DO I DO AFTER THE 24 MONTH COURSE OF FORTEO IS FINISHED?

The recommended time on Forteo is 24 months over a lifetime. This is the time over which Forteo studies in postmenopausal women have been carried out. In these studies, Forteo has been shown to be a safe and effective therapy. It may be that in many patients, a 2 year period of bone building will be sufficient to return bone to its required strength. Subsequently, treatment with one of the bone preserving therapies such as Prolia, Fosamax, Actonel or Aclasta may be sufficient. It is important to know that the building of new bone will continue as you go longer (out to 2 years) with Forteo. After you stop Forteo, you should switch to one of the antiresorptive therapies (such as Fosamax, Actonel, Aclasta or Prolia) in order to maintain the new bone which has been formed. If you do not continue on with an antiresorptive therapy, it is likely that the newly-formed bone will be removed and your bone will return to the state it was previously.

CAN FORTEO BE USED EFFECTIVELY IN PATIENTS PREVIOUSLY TREATED WITH BISPHOSPHONATES?

Bisphosphonates benefit bone by slowing down the activity of the osteoclasts (cells which remove bone) allowing the osteoblasts (bone forming cells) to keep up. In this way, they restore bone turnover to healthier levels, preserving bone, and allowing the existing bone to become harder. The bisphosphonates, however, deposit in the bone and remain there for many years. They therefore have lingering activity even after they have been discontinued. Because of this, bone density usually declines very slowly in patients after stopping bisphosphonate medications. The accumulation of bisphosphonate medication in the bone may blunt or slow the action of Forteo. The increases in bone density in a patient who has previously been on a bisphosphonate are generally slower than in a patient who has not had prior bisphosphonate therapy. There is, however, still a significant bone building response; we just have to wait for a longer time.

IS FORTEO USEFUL FOR FRACTURE HEALING?

Forteo stimulates the formation of new bone. This potentially might have benefits making fractures heal faster. Currently clinical trials of Forteo in patients who have broken a bone are underway. We must await the completion of these trials before we are sure that Forteo is of benefit after breaking a bone. In animal experiments, Forteo has been shown to reduce the time required to heal fractures. At present, Forteo is not approved by Health Canada for use in the healing of fractures.

IS ATYPICAL FRACTURE OF THE FEMUR A RISK OF FORTEO THERAPY? CAN FORTEO BE USED TO TREAT THIS CONDITION?

Atypical femoral fracture (AFF) is a very rare complication in osteoporosis patients treated with bisphosphonate therapy (Fosamax, Actonel, Didrocal, Aclasta) for many years. It has not been reported in the literature with any other osteoporosis therapies. Patients with AFF often have pain in the area of the thigh or hip, beginning several weeks before the AFF. The fracture has the appearance of a stress fracture and is located lower on the thigh bone (femur) than typical hip fractures. The reason why these fractures occur is unknown. In patients who develop an AFF, it is recommended that the bisphosphonate be discontinued. Some have speculated that Forteo might be a good choice of treatment for such patients. Although there are some case reports demonstrating healing of the atypical femoral fracture with Forteo, there are not sufficient studies to date to be sure this is the correct approach.

IS OSTEONECROSIS OF THE JAWS (ONJ) A RISK OF FORTEO THERAPY? CAN FORTEO HELP HEAL OSTEONECROSIS OF THE JAW?

Osteonecrosis of the jaws is a delay in dental healing (more than 8 weeks) usually after a dental extraction or oral surgery. It has been reported in less than 5% of cancer patients given high doses of bisphosphonates or Prolia for the treatment of bone cancer. We are not certain if the lower doses of bisphosphonates used to treat osteoporosis can cause the same delay in dental healing, since it has not been observed in any of the clinical trials. If ONJ is associated with bisphosphonate or Prolia treatment, the risk is extremely low. ONJ usually heals well with non-surgical therapies. In some reported cases, Forteo can help heal such ONJ lesions as well as improve periodontal disease.

DOES FORTEO EFFECTIVELY REDUCE HIP FRACTURES?

Hip fractures occur in the very elderly and are related to both the strength of the hip bone and the likelihood of falling. Studies in younger postmenopausal women or those with less severe osteoporosis have few hip fracture events and so cannot demonstrate hip fracture reduction with therapy. There are a few studies which report fewer hip fractures in high risk elderly patients, with agents such as Fosamax, Actonel, Aclasta, and estrogen. The studies with Forteo did not demonstrate hip fracture reduction, perhaps due to the low number of hip fractures which occurred. In addition, the Forteo fracture trial was short (19 months duration) as compared to the usual 3-year osteoporosis trials. During the fracture trial with Forteo, there were fewer hip fractures in patients treated with Forteo than treated with placebo but the number of fractures was too small to be statistically significant.

CAN I USE FORTEO FOR MORE THAN 24 MONTHS?

The Forteo fracture study was discontinued after about 19 months of treatment. The study was ended owing to studies in rats which showed increased bone cancer (osteosarcoma) after lifelong high-dose Forteo therapy. This finding was not seen in studies of other species of animals. This is one of the reasons that the treatment duration for Forteo was limited to 24 months. To date, osteosarcoma in Forteo patients has not been observed beyond the expected background occurrence. A small trial using Forteo in patients on prednisone therapy was continued to 3 years and showed ongoing benefits to bone. The approved duration of therapy is 2 years. Bone building continues throughout the 2 years and in most patients this is sufficiently long to improve bone strength and reduce the risk of fracture.

IS IT POSSIBLE TO USE FORTEO IN PATIENTS WHO PREVIOUSLY RECEIVED RADIATION THERAPY?

Radiation therapy is useful to treat or to prevent the recurrence of some cancers such as breast and prostate cancer. But radiation may have an effect to change a normal cell into a cancer cell. One of the cancers that rarely occurs after bone radiation is osteosarcoma. This is the same cancer seen in rats treated lifelong with high doses of Forteo. Because we do not know if Forteo might further increase the risk of bone cancer in patients who have had radiation, Forteo should not be used in patients after radiation to bone.

SHOULD FORTEO BE USED IN PATIENTS WITH KIDNEY FAILURE?

Patients with kidney failure have a different bone disease from the usual postmenopausal osteoporosis (called renal osteodystrophy). This is not usually treated with the same medications as postmenopausal osteoporosis. Usually, the kidney specialists will control dietary phosphate intake and give special Vitamin D preparations to help maintain healthy bones in kidney failure patients. Forteo usually should not be used.

WHAT IS OSTEOSARCOMA, WHAT IS MY RISK OF DEVELOPING OSTEOSARCOMA?

Osteosarcoma is a very rare cancer of bone cells. Osteosarcoma was seen in rats treated lifelong with high dose Forteo therapy. It is sometimes seen after radiation treatment to the bone or after a bone disease called Paget's disease. In both of these circumstances, Forteo is not recommended. In the general population at the age when osteoporosis would be treated, the occurrence of osteosarcoma in people not on Forteo is 1 in 300,000. In approximately 1 million patients treated with Forteo over the past 9 years, there have been a similar number of osteosarcoma cases(ie no excess number of cases). This reassures us that after 2-years of treatment with Forteo in older adults, there has not been an excess of osteosarcoma cases seen.

CAN FORTEO CAUSE LIGHT-HEADEDNESS, NAUSEA, MUSCLE CRAMPS AND ARTHRALGIA? HOW SHOULD I MANAGE THIS?

Common side effects of Forteo therapy can include light-headedness, nausea, muscle cramps and joint pains. Usually these symptoms are mild and go away within 3 weeks if treatment is continued. Some patients have found alternate day dosing for a week or two, then going to daily dosing will help deal with the symptoms. Others have benefitted from dosing Forteo at bedtime. In Canada, almost 90% of patients are still taking Forteo one year after starting the therapy. This indicates the mild and temporary nature of these symptoms in most patients.

WHAT CAN I DO IF I AM AFRAID OF NEEDLES?

Forteo currently can only be given by injection since the medication is not absorbed if given orally. The needles used are extremely fine and very sharp making the discomfort of injection minimal. It often helps to practice injection technique with a nurse to be sure you are confident. Most people, like those with diabetes who require insulin, learn how to inject easily and find injections a minor inconvenience, at most.

DOES MY BLOOD CALCIUM NEED TO BE MONITORED WHILE I AM ON FORTEO?

Forteo can result in a small rise in the blood calcium level for several hours after the injection and then usually a return back to normal. In the clinical studies, there was no harm or symptoms seen in this short period of elevated blood calcium. There was also, in some patients, a small increase in the urine calcium, again without any symptoms. These effects are evidence that the medication is having its effect on the bone. There is no required monitoring of blood or urine calcium in patients taking Forteo. If your doctor wishes to test blood calcium, be sure it is a fasting sample at least 24 hours after your last Forteo injection.

WHAT IS SIGMA?

SIGMA (Special Interest Group on Menopause and Aging) is the Canadian Menopause Society. We are a multidisciplinary group of family physicians, specialists and healthcare professionals who are interested in menopausal health. Our mission is to advance the health of women at and beyond the menopause transition through education initiatives and knowledge transfer.

SIGMA is a hub of menopausal knowledge with the ability to transfer information on a wide range of issues. It networks with menopause clinic(s) and menopause practitioners across Canada to share knowledge; to act as advocate(s) for menopausal health in Canada; and to provide up-to-date knowledge to our patients.

SIGMA strives to have one voice in Canada that speaks for the women in Canada.SIGMA is linked internationally to the North American Menopause Society (NAMS) and to the International Menopause Society (IMS). SIGMA members also liaise with the Society of Obstetricians and Gynecologists of Canada (SOGC), the Canadian College of Family Practice (CCFP), Osteoporosis Canada (OC) and the Federation of Medical Women of Canada (FMWC).

For references and additional information, please visit us at

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This brochure was made possible through financial support by
Eli Lilly Canada.