

Romosozumab

Romosozumab is the newest anti-fracture medication to become available (Canadian market release June 2019). This is a new type of medication that falls into what are called "anabolic" therapies because of their ability to build new bone [teriparatide is the other anabolic osteoporosis medication on the market]. Romosozumab works by inhibiting a hormone called sclerostin which normally limits the amount of new bone formed. In other words, this therapy helps by "taking your foot off the brake of new bone formation."

What is it called?

Romosozumab (EVENITY®)

What does it do?

This medication builds new bone and reduces bone loss thereby decreasing the risk of fractures.

How do I take it?

This medication is given as two subcutaneous (under the skin) injections, every month. These injections may be given by your community pharmacist, primary healthcare provider, or yourself. If you choose to do self-injection, training can be provided by the patient support program.

How long do I take it for?

Romosozumab is taken once a month, consecutively, for 12 months. After the 1 year treatment period, many physicians recommend follow up treatment with another medication (such as a bisphosphonate) to maintain the benefits of Romosozumab.

Who should not take this medication?

People with recent heart problems, such as heart attack or stroke and those with low blood calcium levels should not take Romosozumab.

What side effects might be possible?

Romosozumab is generally very well tolerated; in clinical studies, it did not seem to cause any symptomatic side effects any differently than a placebo injection with the exception of a 5% chance of local skin irritation from the injection. Headache and joint pains have been seen on occasion. It only builds bone in your existing normal skeleton (i.e. it does not cause bone formation or calcification in other parts of your body).

There is however ongoing controversy about whether Romosozumab might be linked to a small increase in the risk of heart attack or stroke. This is an issue which has been very carefully studied over the past few years and even still there is no clear agreement among bone scientists. The issue arose during the course of 2 very large clinical trials done in older women with osteoporosis. In one clinical trial, half the women received Romosozumab and half received placebo injections for 1 year; in this trial, there was no sign of heart disease or stroke. In the other clinical trial, half the women received Romosozumab and half received alendronate for 1 year and in this trial, there was a small increase in the risk of heart attack or stroke in the Romosozumab group. The amount of risk increase was less than 1% but it was still not zero. Despite many subsequent experiments, scientists have not been able to come up with any kind of explanation as to why this might have happened with this drug and so there is an ongoing debate about whether the increased heart attack/stroke risk is real or just a chance occurrence that happened to show up in that second trial. For now, to be on the safe side, this medication is "not recommended" for women with a history of prior heart attack or stroke. For those who have not had heart attack or stroke but who are at high risk of heart disease/stroke, a careful discussion about risk/benefit should be had with your physician.

What are the costs involved?

Romosozumab costs ~ \$840 per month (\$10 000 per year). This medication is covered by some drug plans. Alberta Seniors Blue Cross does not currently cover Romosozumab.