



Osteoporosis Canada

Ostéoporose Canada

Fosamax and atrial fibrillation: Osteoporosis Canada responds

We are aware of recent press reports concerning the link between two drugs for osteoporosis (alendronate and zoledronate) and the occurrence of a heart condition characterized by an irregular heart beat (atrial fibrillation).

We recognize that you might find these reports concerning. Osteoporosis Canada takes your concerns seriously and we will continue to be vigilant in order to inform you about the latest research. The study cited in the newspaper articles has been reviewed by experts from the Scientific Advisory Committee at Osteoporosis Canada and their response is below.

It is a fact - all medications have risks associated with them. Osteoporosis medications are no exception. Every time a physician recommends and prescribes a medication, it includes carefully weighing the risks and benefits of taking a medication.

The study referenced above reported that among 719 women with atrial fibrillation 47 had used alendronate whereas among 966 women without atrial fibrillation 40 had used alendronate. The authors concluded that use of alendronate was associated with an increased risk of atrial fibrillation.

This study has some limitations, which were discussed by the authors but not mentioned in media reports, which should lead us to interpret the findings with caution. Two major limitations are the small number of women using alendronate and the fact that this was not a randomized controlled trial - as such it is not possible to state that alendronate causes atrial fibrillation.

To date, atrial fibrillation has not been reported with other commonly used osteoporosis medications including related bisphosphonates such as risedronate and etidronate. Other studies, evidence and data support that the notion that **atrial fibrillation associated with bisphosphonate use is extremely rare.**

Fractures (broken bones) due to osteoporosis, on the other hand, are extremely common. Osteoporotic fractures are linked to additional fractures, altered quality of life, worsening of other health conditions and in some cases – death. Bisphosphonate medications provide protection from osteoporotic fractures. It is important to remember that your physician carefully weighs the risks and benefits of taking a medication for your unique situation every time he or she recommends and prescribes a medication. Your healthcare team is available to review any concerns or questions you may have about this issue.

NOTE: On November 12, 2008, the FDA released its most recent conclusion regarding the association between bisphosphonates and atrial fibrillation. In its communication, the FDA emphasizes "no clear association between overall bisphosphonate exposure and the rate of serious or non-serious atrial fibrillation". Please note that this is a US update and updated information from Health Canada is not currently available.

To read the entire summary of this conclusion, please follow this link:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#bisphosphonates2>

For the full article on "Update of Safety Review Follow-up to the October 1, 2007 Early Communication about the Ongoing Safety Review of Bisphosphonates", please follow this link:

http://www.fda.gov/cder/drug/early_comm/bisphosphonates_update_200811.htm

These statements are US update. Updated information from Health Canada, if available, will be provided accordingly.