

# No difference in brand name and generic drugs regarding thyroid dysfunction

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There is no difference between brand-name and generic drug formulations of amiodarone -- taken to control arrhythmia – in the incidence of thyroid dysfunction, according to a study in *CMAJ* (*Canadian Medical Association Journal*).

Amiodarone, prescribed to control irregular heartbeats, is known for causing hypo- and hyper-thyroidism. Amiodarone is available in Canada in [brand-name](#) formulations as well as less costly generic versions. Generic formulations may be substituted if considered bioequivalent to the brand name drug. However, in some drugs there are concerns that generic formulas may be less effective or increase the number of adverse events.

[Thyroid dysfunction](#) occurs in one in five [patients](#) on amiodarone.

There is no information on the effects of brand-name versus generic versions of amiodarone on the incidence of thyroid dysfunction. Researchers from McGill University Health Centre and Jewish General Hospital, Montreal, Quebec; Western University of Health Sciences, Pomona, California; University of British Columbia, Vancouver, BC and the Institute for Clinical Evaluative Sciences in Toronto, Ontario sought to examine the incidence of thyroid dysfunction in patients taking brand name formulations of amiodarone compared with generic versions.

They looked at data on 60 220 patients aged 66 and older with atrial fibrillation taking amiodarone. Of these, 2804 (4.7%) used the brand-

name formulation and 6278 (10.4%) took the generic formulation. There was no significant difference in rates of thyroid dysfunction between the two groups, measured in hospital admissions, visits to physicians for the condition or taking drugs for thyroid dysfunction.

"The incidence rate for thyroid dysfunction was estimated at 14.1 per 100 person-years, similar for both formulations," writes Dr. Louise Pilote, physician and researcher at the McGill University Health Center, with coauthors. "The incidence rates for hypothyroidism and hyperthyroidism per 100 person-years were comparable between brand-name and generic formulations, with hypothyroidism occurring more commonly than hyperthyroidism."

They caution that patients should be warned of the risks of amiodarone when they begin the drug so they can recognize and report symptoms.

"We found no difference in the incidence of thyroid dysfunction between generic and brand-name formulations," conclude the authors. "The results from this study provide valuable information for both clinicians and policy makers concerning the prescription of brand name versus generic drugs."

In a related commentary, Dr. Aaron Kesselheim of Brigham and Women's Hospital in Boston states, "Decades of experience and numerous clinical studies suggest that patients and physicians can be confident in the bioequivalence of brand-name and generic drugs approved by Health Canada, the FDA or other similar regulatory authorities. In the rare circumstances where there is concern over interchangeability, such as for high-risk patients, it may be reasonable for physicians to take extra precautions, such as additional monitoring, when substitution occurs."

Provided by Canadian Medical Association Journal

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