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332 7

2

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Osteoporosis: Original Article

The effect of mandatory generic substitution on the safety of alendronate and patients' adherence

Pauline Siew Mei Lai

, Siew Siang Chua, Yah Huei Chong & Siew Pheng Chan
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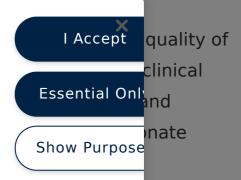
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This prospective study involved two groups of patients: (1) postmenopausal osteoporotic women prescribed once-weekly Fosamax (proprietary group) but were switched to apo-alendronate after 2 years ('switched over' group); and (2) patients initiated with once-weekly apo-alendronate (generic group). Participants were recruited from the Osteoporosis Clinic of a tertiary hospital. Data were collected through interviews.

Main outcome measures:

Side-effects and medication adherence.

Results:

A total of 131 participants were recruited: proprietary group = 64 and generic group = 67. An intergroup and a within-group comparison were made. Side-effects were reported by 6 (9.4%), 30 (44.8%) and 12 (18.8%) participants in the proprietary, generic and 'switched over' groups, respectively. Participants who were on generic alendronate were at a significantly higher risk of experiencing side-effects compared to those who were taking proprietary alendronate [odds ratio (OR):7.84 (95% CI: 2.98–20.65), p < 0.001]. However, no significant statistical difference was found between the 'switched over' and the proprietary group [OR: 2.23 (95% CI: 0.78–6.37), p = 0.127]. Four out of 12 (33.3%) patients who experienced side-effects immediately after switching to generic alendronate discontinued generic alendronate due to intolerable gastrointestinal side-effects. There was no difference in medication adherence to generic or proprietary alendronate.

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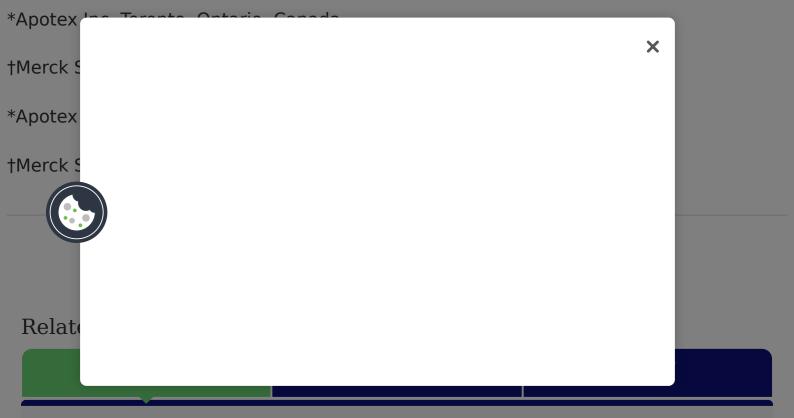
The authors declare that they have no competing interests. CMRO peer reviewers on this manuscript have no relevant financial relationships to disclose.

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This material has not been previously published except as an abstract in the 2nd International Conference on Pharmacy and Advanced Pharmaceutical Sciences, Yogyakarta, Indonesia, 19–20 July 2011, abstract no P10: 64.

Notes



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