

[2006] [FRI0431] UPPER GASTROINTESTINAL SAFETY AND TOLERABILITY PROFILE OF ONCE-MONTHLY AND DAILY ORAL IBANDRONATE: MOBILE 2-YEAR ANALYSIS

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Background: Upper gastrointestinal (GI) adverse events (AEs) are experienced by some patients taking oral bisphosphonates. Previously, daily and intermittent (dosing interval >2 months) oral ibandronate regimens were shown to have an upper GI AE profile similar to placebo in women with postmenopausal osteoporosis, even in patients at increased risk for such events.¹ A similar profile was obtained with once-monthly oral dosing at 1 year in the MOBILE study.² Additional analyses were performed at 2 years to firmly establish the upper GI safety and tolerability profile of once-monthly ibandronate.

Methods: MOBILE was a randomised and double-blind study that compared the efficacy and safety of various once-monthly oral ibandronate regimens (50+50mg, 100mg or 150mg) with the established daily oral schedule (2.5mg). All participants were women aged 55–80 years and ≥5 years since menopause. Baseline lumbar spine bone density T-scores were between <–2.5 and ≥–5.0. All participants received daily vitamin D (400IU) and calcium (500mg). Upper GI AEs were continuously monitored.

Results: In total, 1,609 women participated. Similar to the result at 1 year, a comparable rate of upper GI AEs was observed across the treatment arms at 2 years (19.9–25.8%). As expected, upper GI AEs were generally more frequently observed in patients with prior history of upper GI disorder. However, apart from a lower incidence in patients with a prior history receiving the 150mg regimen (27.1%), rates were generally comparable across groups in those with and without a recorded history of upper GI complaint (45.2–48.9% and 16.2–23.3%, respectively). The frequency of upper GI AEs was also generally similar across treatment arms in patients receiving concurrent non-steroidal anti-inflammatory drugs (NSAIDs; 26.1% for daily vs 23.6–31.2% for monthly) and/or proton-pump inhibitors or H2 blockers (61.5% for daily vs 53.8–66.7% for monthly). In both analyses, the lowest rate was again observed with the 150mg regimen. In all treatment arms, the incidence of serious upper GI AEs (0.5–1.3% across all arms) and associated withdrawals (0–0.5% across all arms) was low.

Conclusion: Once-monthly oral ibandronate shares a similar upper GI safety and tolerability profile with the established daily oral ibandronate schedule, even in patients predisposed to upper GI complaints. This result is noteworthy, as the daily regimen has previously shown safety and tolerability similar to placebo.

References: 1. Chesnut CH, et al. J Bone Miner Res 2004;19:1241–9.

2. Miller PD, et al. J Bone Miner Res 2005;20:1315–22.

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