

Alendronate/Colecalciferol

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While there remains confusion about the levels of 25-hydroxyvitamin D₃ that are adequate for optimum skeletal health, recent evidence indicates that vitamin D 800–1000 IU/day is needed for adults to maintain an optimum serum level of 25-hydroxyvitamin D₃. No matter what levels have been critically evaluated, it is clear that vitamin D insufficiency/deficiency is far more prevalent than previously suspected. Appropriately, with limited exceptions, all registration trials for drugs that are FDA approved in the US, and by corresponding regulatory bodies in other countries, were conducted with subjects in both the active and placebo arms being given supplemental calcium and/or vitamin D. The product labeling for bisphosphonates includes a statement that patients should take supplemental calcium and vitamin D during their course of therapy. Market surveys and some published reports point out that many patients are not following this recommendation.

The once-weekly administration of a single tablet that delivers both alendronate and colecalciferol 2800IU may have the advantage of ensuring delivery of vitamin D on a single weekly sched-

ule. Studies indicate that bioavailability and tolerability of this combination are similar to alendronate alone. This regimen may increase the compliance of patients, particularly the elderly patients with vitamin D deficiency and memory loss.

However, several key questions remain unanswered:

- “Will patients remember to take their daily supplement of calcium?”

- “Is a weekly dose of vitamin D 2800IU enough for most patients or should they continue to take a daily vitamin D supplement?” This will be an expensive question to answer because a laboratory measurement of 25-hydroxyvitamin D is substantially more expensive than a daily supplement of 400–800 units in addition to the weekly 2800IU.

- “How will patients react now that they know that they can reliably take a single tablet containing both vitamin D and alendronate?” For years, patients have been told that they should not take any food or beverage (other than water) or other medications for 30 minutes after taking their once-weekly alendronate.

Although once-weekly alendronate/colecalciferol seems to be safe and effective, physicians will still have to remain vigilant about informing their patients how to take the alendronate/colecalciferol tablet as prescribed and remain equally vigilant about reminding patients to take supplemental calcium. ▲