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On Drugs and Therapeutics

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IN BRIEF

Delayed-Release Risedronate (*Atelvia*)

A new enteric-coated delayed-release formulation of risedronate (*Atelvia* – Warner Chilcott) has been approved by the FDA for treatment of postmenopausal osteoporosis. Unlike immediate-release risedronate (*Actonel*) and all other oral bisphosphonates, which must be taken after an overnight fast and at least 30 minutes before eating breakfast, the new formulation is taken immediately after breakfast with at least 4 ounces of water. Then the patient must remain upright for at least 30 minutes.

CLINICAL TRIAL — Approval of *Atelvia* was based on a 52-week non-inferiority study in more than 900 postmenopausal women comparing the new 35-mg delayed-release tablet taken once each week to the original immediate-release 5-mg tablet taken daily at least 30 minutes before breakfast. (FDA approval of risedronate was based on studies with the 5-mg tablet taken once daily; now *Actonel* is usually taken, like *Atelvia*, as a 35-mg tablet once a week.) Increases in bone mineral density at the lumbar spine and other locations and changes in markers of bone turnover were similar in both groups. Diarrhea and abdominal pain occurred more frequently with the new formulation once weekly after breakfast than with risedronate 5 mg daily (8.8% vs. 4.9% and 5.2% vs. 2.9%, respectively).¹

DOSAGE AND COST — *Atelvia* is available as a 35-mg tablet taken once each week. A month's supply of the new formulation (four 35-mg tablets) costs \$119.99, which is similar to the cost of *Actonel* once a week (\$126.47).² Alendronate (*Fosamax*, and others) is currently the only bisphosphonate available generically that is FDA-approved for treatment of osteoporosis; a month's supply is available at some discount pharmacies for \$9.

CONCLUSION — Taking the new enteric-coated delayed-release formulation of risedronate (*Atelvia*) after breakfast presumably would be more convenient than taking immediate-release risedronate 30 minutes before breakfast, but it may cause more diarrhea. Generic alendronate costs much less than either one.

1. MR McClung et al. BMD response to delayed-release risedronate 35 mg once-a-week formulation taken with or without breakfast. *J Clin Densitom* 2010; 13:132; Poster number 067.
2. Cost at drugstore.com. Accessed March 14, 2011.

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Correction: In Brief: Delayed-Release Risedronate (Atelvia) (Med Lett Drugs Ther 2011; 53:24)

The In-Brief article on delayed-release risedronate in issue 1360 included a statement that alendronate is currently the only bisphosphonate available generically. That would have been accurate if we had added "that is FDA-approved for treatment of osteoporosis." Etidronate (*Didronel*, and others), which was the first bisphosphonate used to treat osteoporosis ([Medical Letter 1990; 32:111](#)) but was never approved for such use by the FDA, is also available generically. It is approved for treatment of Paget's disease and for prevention and treatment of heterotopic ossification following hip replacement and in spinal-cord injured patients.

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