

# FDA Approves Generic Fosamax®

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ROCKVILLE, Md., Feb. 6, 2008--The U.S. Food and Drug Administration today approved the first generic versions of Fosamax (alendronate sodium tablets), used to treat osteoporosis, a condition that causes thinning and weakening of a person's bones.

Teva Pharmaceuticals USA, North Wales, Pa., was approved to manufacture alendronate sodium tablets in three once-daily dosing strengths (5 milligrams, 10 milligrams, and 40 milligrams) and two once-weekly dosing strengths (35 milligrams and 70 milligrams). Barr Laboratories, Inc., Montvale, N.J., was approved to manufacture a 70 milligrams once-weekly dose of the drug.

"The FDA works to assure the safety and efficacy of generic drugs through a rigorous scientific and regulatory process," said Gary J. Buehler, R.Ph, director of the FDA's Office of Generic Drugs. "These approvals will provide generic options for patients who take Fosamax for their osteoporosis."

Fosamax is among the top 100 most frequently dispensed drugs in the United States, according to the trade magazine Drug Topics.

Generic drug manufacturers must demonstrate that a generic drug has the same active ingredient, dosage form, strength, route of administration, quality and performance characteristics, among other things, as the approved brand-name drug.

The labeling of the generic alendronate sodium tablets may differ from that of Fosamax because some portions of the labeling are protected by patents and exclusivity.

For more information visit FDA's Office of Generic Drugs  
[www.fda.gov/cder/consumerinfo/generic\\_equivalence.htm](http://www.fda.gov/cder/consumerinfo/generic_equivalence.htm)