Generic alendronic acid approved for osteoporosis in the US

The first generic versions of **alendronic acid** [Fosamax; Merck & Co] have been approved by the US FDA for the management of osteoporosis, and are now available.[1,2]

Teva Pharmaceutical Industries' New Drug Application was granted final approval from the FDA for generic alendronic acid 5mg, 10mg, 35mg, 40mg and 70mg tablets.[1] Barr Laboratories' application for alendronic acid 70mg tablets has also received final approval from the FDA, following the expiration of paediatric exclusivity associated with the earliest to expire of the patents listed with FDA for Fosamax.[2] This product is indicated for the treatment and prevention of osteoporosis in postmenopausal women, to increase bone mass in men with osteoporosis, to treat glucocorticoid-induced osteoporosis and to treat Paget's disease of bone.

Fosamax tablets reportedly had annual sales of around $US1.7 billion for the 12 months ended November 2007 in the US. Barr and Teva are both entitled to 180 days of marketing exclusivity for their alendronic acid products.

1. Barr Pharmaceuticals Inc. Barr Launches Generic Fosamax(R) Tablets, 70 mg. Media Release : 6 Feb 2008. Available from: URL: http://www.barrlabs.com.
2. Teva Pharmaceutical Industries Ltd. Teva Announces Approval of Generic Fosamax(R) Tablets, 5 mg, 10 mg, 35 mg, 40 mg and 70 mg. Media Release : 7 Feb 2008. Available from: URL: http://www.teva.com.

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