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On Drugs and Therapeutics

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IN BRIEF

Budeprion XL 300 Has Been Withdrawn

The FDA has asked Impax Laboratories/Teva Pharmaceuticals to stop production and distribution of *Budeprion XL 300 mg*, a generic extended-release formulation of the antidepressant bupropion (*Wellbutrin XL*), because it has found that *Budeprion XL 300 mg* releases bupropion more rapidly than *Wellbutrin XL 300 mg*, the original brand name product. Patients switched from the brand name to the generic formulation have complained for years that the generic was less effective and caused more side effects than the original formulation. In 2007, ConsumerLab.com, an independent laboratory, conducted dissolution testing of *Budeprion XL*, which uses a matrix for slow release, and *Wellbutrin XL*, which uses a membrane. According to the test results, the *Budeprion XL* matrix released more bupropion in the first 4 hours than the *Wellbutrin XL* membrane did.¹ The FDA decided to conduct its own studies of *Budeprion XL 300 mg* and arrived at a similar conclusion. The original approval of the generic formulation was based on pharmacokinetic tests conducted on 150-mg tablets of the Impax/Teva formulation, with results extrapolated to the 300-mg tablet.

Bupropion is often used as an alternative to a selective serotonin reuptake inhibitor (SSRI) or another antidepressant because it does not cause sexual dysfunction, sedation, or weight gain.² It is also used as an aid in smoking cessation.³ It is contraindicated in patients at increased risk of seizures (including patients with a history of an eating disorder). Other 300-mg formulations of generic extended-release bupropion have not been associated with post-marketing complaints and continue to be available.

1. Wellbutrin versus generic bupropion. *Med Lett Drugs Ther* 2008; 50:54.
2. Drugs for depression and bipolar disorder. *Treat Guidel Med Lett* 2010; 8:35.
3. Drugs for tobacco dependence. *Treat Guidel Med Lett* 2008; 6:61.

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