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On Drugs and Therapeutics

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IN BRIEF

Tegaserod (*Zelnorm*) Withdrawn

Tegaserod maleate (*Zelnorm* – Novartis), a partial serotonin 5-HT₄ receptor agonist that increases gastrointestinal motility, was approved by the FDA in 2002 for short-term treatment of constipation-predominant irritable bowel syndrome in women,¹ and in 2004 for treatment of chronic constipation in adults ≤65 years old. Its efficacy has not been impressive statistically, but according to Medical Letter consultants some patients with slow-transit constipation have benefited from taking the drug. Diarrhea has been its main adverse effect.²

The FDA now has requested that the manufacturer stop marketing the drug based on an unpublished postmarketing analysis of earlier clinical trials that showed a higher rate of serious cardiovascular events (including angina, myocardial infarction and stroke) in patients who took tegaserod compared to placebo. Among more than 11,600 patients treated with tegaserod for 1-3 months, 13 (0.11%) had a confirmed ischemic event compared to only 1 patient (0.01%) among more than 7000 treated with placebo. The mechanism by which tegaserod would cause cardiovascular ischemia is unknown; serotonin 5-HT₁ receptor agonists used to treat migraine, such as sumatriptan (*Imitrex*), can constrict coronary arteries, and tegaserod has some affinity for 5-HT₁ receptors.³

Tegaserod may still be available, possibly through a special access program, for patients who do not have other treatment options.

1. Tegaserod maleate (*Zelnorm*) for IBS with constipation. *Med Lett Drugs Ther* 2002; 44:79.
2. Drugs for irritable bowel syndrome. *Treat Guidel Med Lett* 2006; 4:11.
3. AJ Busti et al. Tegaserod-induced myocardial infarction: case report and hypothesis. *Pharmacotherapy* 2004; 24:526.

Coming Soon in *The Medical Letter*:

Lisdexamfetamine (*Vyvanse*) for ADHD

Lapatinib (*Tykerb*) for Breast Cancer

Sunscreens

Coming Soon in *Treatment Guidelines*:

Choice of Antibacterial Drugs – May 2007

Drugs for Cardiac Arrhythmias – June 2007

Drugs for Non-HIV Viral Infections – July 2007

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