FDA Approves Injectable Drug to Treat Opioid-Dependent Patients

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U.S. Food and Drug Administration →
Oct 12, 2010, 06:54 ET

SILVER SPRING, Md., Oct. 12 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration today approved Vivitrol to treat and prevent relapse after patients with opioid dependence have undergone detoxification treatment.

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Vivitrol is an extended-release formulation of naltrexone administered by intramuscular injection once a month. Naltrexone works to block opioid receptors in the brain. It blocks the effects of drugs like morphine, heroin, and other opioids. It was approved to treat alcohol dependence in 2006.

"Addiction is a serious problem in this country, and can have devastating effects on individuals who are drug-dependent, and on their family members and society," said Janet Woodcock, M.D., director of FDA's Center for Drug Evaluation and Research. "This drug approval represents a significant advancement in addiction treatment."

The safety and efficacy of Vivitrol were studied for six months, comparing Vivitrol treatment to placebo treatment in patients who had completed detoxification and who were no longer physically dependent on opioids. Patients treated with Vivitrol were more likely to stay in treatment and to refrain from using illicit drugs. Thirty-six percent of the Vivitrol-treated patients were able to stay in treatment for the full six months without using drugs, compared with 23 percent in the placebo group.

Patients must not have any opioids in their system when they start taking Vivitrol; otherwise, they may experience withdrawal symptoms from the opioids. Also, patients may be more sensitive to opioids while taking Vivitrol at the time their next scheduled dose is due. If they miss a dose or after treatment with Vivitrol has ended, patients can accidentally overdose if they restart opioid use.

Side effects experienced by those using Vivitrol included nausea, tiredness, headache, dizziness, vomiting, decreased appetite, painful joints, and muscle cramps. Other serious side effects included reactions at the site of the injection, which can be severe and may require surgical intervention, liver damage, allergic reactions such as hives, rashes, swelling of the face, pneumonia, depressed mood, suicide, suicidal thoughts, and suicidal behavior.

Vivitrol should be administered only by a physician as an intramuscular injection, using special administration needles that are provided with the product. Vivitrol should not be injected using any other needle. The recommended dosing regimen is once a month.

Consumers and health care professionals are encouraged to report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/how.htm.

Vivitrol is manufactured by Alkermes, Inc.

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Consumer Inquiries: 888-INFO-FDA

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