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Topic: Important Change to the Patient Package Insert for VIVITROL® (naltrexone for extended-release injectable suspension) - New Medication Guide

Dear Healthcare Professional:

Alkermes is writing to inform you that a Medication Guide has been developed that replaces the Patient Package Insert for VIVITROL. In June 2009, Alkermes updated the Warnings, the Information for Patients, and the Dosage and Administration sections of the VIVITROL Prescribing Information to strengthen language regarding the risk of injection site reactions based on postmarketing reports that had been received prior to that date. At that time, the U.S. Food and Drug Administration requested that Alkermes develop the enclosed Medication Guide, which communicates this and other important information about treatment with VIVITROL.

The Medication Guide provides important information patients should know about VIVITROL, including side effects, who should not take VIVITROL, what patients should tell their healthcare professional before starting VIVITROL and what they should avoid while taking VIVITROL.

Patients should be promptly provided with the Medication Guide and instructed to read the Medication Guide before starting VIVITROL and before each injection. Patients should be encouraged to ask questions about what they've read.

Healthcare professionals should also counsel patients about the risks and benefits of VIVITROL before an initial prescription, including those risks and benefits set forth in the new Medication Guide and Prescribing Information, and should ensure that patients understand these risks.

At Alkermes, patient safety is our highest priority and we are committed to providing healthcare professionals with information to guide the safe and appropriate use of VIVITROL.

We also encourage you to report any serious adverse events in patients treated with VIVITROL to Alkermes, Inc. by telephone at 1-800-VIVITROL (1-800-848-4876) (option #1) or by email at usmedinfo@alkermes.com. Alternatively, this information may be reported to FDA's MedWatch Reporting System by phone at 1-800-332-1088, by mail using the Form 3500 at http://www.fda.gov/medwatch/index.html, or online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm.

Enclosed please find copies of the Prescribing Information and new Medication Guide for VIVITROL. This information is also available on the product website (www.vivitrol.com) or by contacting 1-800-VIVITROL (1-800-848-4876) (option #1).

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Thank you,

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Enclosure: VIVITROL – Full prescribing information

www.vivitrol.com