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December 8, 2015

IMPORTANT DRUG WARNING

Subject: VIVITROL[®] (naltrexone for extended release injectable suspension)

- **Risk of Severe Injection Site Reactions**
- **New Patient Counseling Tool and Safety Poster**

Dear Healthcare Provider:

The purpose of this letter is to inform you of important new safety information for VIVITROL (naltrexone for extended-release injectable suspension). VIVITROL is a prescription injectable medicine used to treat alcohol dependence and for the prevention of relapse to opioid dependence following opioid detoxification.

Severe injection site reactions continue to occur. In addition, a recent assessment demonstrated that patients are not fully aware of the serious risks associated with the use of VIVITROL. Therefore, the FDA has modified the VIVITROL Risk Evaluation and Mitigation Strategy (REMS) to highlight the potential risk of severe injection site reactions and to emphasize the importance of healthcare providers counseling their patients about the serious risks associated with VIVITROL.

The REMS program now includes the following:

Patient Counseling Tool

A patient counseling tool has been created for prescribers to use when counseling their patients about the serious risks associated with the use of VIVITROL. Prescribers should remember to counsel their patients about the serious risks, including any relevant signs and symptoms, associated with the use of VIVITROL, including the following:

- risk of opioid overdose
- serious risk of severe injection site reactions
- risk of precipitated opioid withdrawal (new Warning: see enclosed Prescribing Information)
- risk of hepatotoxicity, including hepatitis
- possibility that patients may not feel the therapeutic effects of opioid-containing medicines for pain, cough, and diarrhea while taking VIVITROL.

Poster: Key Techniques to Reduce Severe Injection Site Reactions

Severe injection site reactions have been reported in the postmarketing period with the following features: induration, cellulitis, hematoma, abscess, sterile abscess, and necrosis. Some cases have required hospitalization and surgical intervention, including debridement of necrotic tissue, and have resulted in significant scarring.

The *Directions for Use* section in the Prescribing Information has been revised to include additional detail regarding how to inject VIVITROL. The following three recommendations may help decrease the risk of severe injection site reactions for VIVITROL:

1. Proper needle selection

Select the 2-inch needle for patients with more subcutaneous adipose tissue. Select the 1 1/2 inch needle for patients with less subcutaneous adipose tissue. Use either needle for patients of average body habitus. The correct needle-length is required to ensure VIVITROL is injected into the gluteal muscle.

2. Proper aseptic technique

Ensure you are using proper aseptic injection technique when administering VIVITROL as described in the *Directions for Use* section in the Prescribing Information.

3. Proper Intramuscular (IM) injection

Administer VIVITROL intramuscularly into the gluteal muscle of the buttock. VIVITROL must NOT be administered intravenously or subcutaneously.

A VIVITROL visual aid poster is available to emphasize the importance of proper administration of VIVITROL. The poster, titled *Key Techniques to Reduce Severe Injection Site Reactions*, **includes proper needle selection, proper aseptic technique, and proper intramuscular injection technique**. This poster should be displayed in your office in the area where VIVITROL injections are administered.

VIVITROL REMS website

You can find more information and materials at the VIVITROL REMS website at www.vivitrolrems.com

Medication Guide

The Medication Guide contains information to support patient education regarding the risks and benefits of treatment with VIVITROL. **The VIVITROL Medication Guide must be provided to patients before each administration of VIVITROL.**

How do I Order Free Copies of Materials?

For copies of the Patient Counseling Tool, *Key Techniques to Reduce Severe Injection Site Reactions* Poster, and/or Medication Guide please contact Alkermes at www.vivitrolrems.com or by calling 1-800-848-4876, Option #1.

Reporting Adverse Reactions

To report any adverse events with the use of VIVITROL contact:

- Alkermes at 1-800-848-4876 (option#1) or by email at usmedinfo@alkermes.com, or
- FDA's MedWatch Reporting System by phone at 1-800-332-1088, or online at www.fda.gov/medwatch/report.htm.

This letter is not a comprehensive description of the risks and benefits associated with the use of VIVITROL. **Healthcare Providers must read the accompanying Prescribing Information, for a complete description of VIVITROL.**

For additional information, please call Alkermes at 1-800-848-4876 (option #1) or visit usmedinfo@alkermes.com.

Thank you,



Bernard L. Silverman, M.D.
Vice President, Drug Safety and Medical Affairs
Alkermes, Inc.

Enclosures: VIVITROL Prescribing Information
 VIVITROL Medication Guide
 VIVITROL Patient Counseling Tool
 VIVITROL *Key Techniques To Reduce Severe Injection Site Reactions* Poster

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