

Initial REMS Approved: March 2010

Most Recent Modification: 05/2016

NDA 21-897 VIVITROL[®] (naltrexone for extended-release injectable suspension)
Opioid Antagonist

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RISK EVALUATION AND MITIGATION STRATEGY (REMS)

I. GOALS

The goals of this REMS are:

- To inform patients and healthcare providers about severe injection site reactions associated with the use of VIVITROL.
- To inform healthcare providers about the importance of counseling their patients about severe injection site reactions associated with the use of VIVITROL.

II. REMS Elements

A. Medication Guide

A Medication Guide will be included with each VIVITROL package in accordance with 21 CFR 208.24.

The [Medication Guide](#) is part of the REMS and is appended.

B. Communication Plan

A Communication Plan will be implemented for those healthcare providers who are likely to prescribe and/or inject VIVITROL. This Communication Plan will consist of the following components:

1. Dear Healthcare Provider Letter

Within 60 days of the modified REMS approval date, (July 29, 2013) a *Dear Healthcare Provider (DHCP) Letter* will be distributed to all healthcare providers who are likely to prescribe and/or inject VIVITROL as ascertained through the Touchpoints database, specialty pharmacy data, and third party data. Annually, for 3 years following approval of the modified VIVITROL REMS (July 29, 2013), Alkermes will identify new prescribers of VIVITROL who were not previously sent the *DHCP Letter* and will distribute *DHCP Letter* to these prescribers.

The *DHCP Letter* will be distributed electronically (via email) or by the US Postal Service. The *DHCP Letter* will inform healthcare providers of the serious risks associated with VIVITROL, especially the continued occurrence of serious injection site reactions. It will also reinforce the importance of healthcare providers discussing the risks of VIVITROL with their patients and providing their patients with a copy of the Medication Guide. The full VIVITROL Prescribing Information, Medication Guide, *Key Techniques to Reduce Severe Injection Site Reactions* Poster and VIVITROL Patient Counseling Tool will accompany the *DHCP Letter*.

In addition, the field sales force will provide a copy of the *DHCP Letter* to each healthcare provider upon whom they call and it will be available on the VIVITROL REMS website (www.vivitrolrems.com) for 3 years following approval of the modified VIVITROL REMS, (July 29, 2013).

The *DHCP Letter* is appended.

2. Prescriber tool to facilitate counseling/educating patients (VIVITROL Patient Counseling Tool)

Alkermes will provide healthcare providers with the VIVITROL *Patient Counseling Tool* that will be in the form of a two-page document highlighting important risks associated with VIVITROL use.

This tool will be distributed beginning within 60 days after the modified REMS approval date, (July 29, 2013) with the *DHCP Letter*. It will be distributed by the sales force to each healthcare provider upon whom they call and it will be available on the VIVITROL REMS website (www.vivitrolrems.com) for 3 years following approval of the modified VIVITROL REMS, (July 29, 2013).

The VIVITROL *Patient Counseling Tool* is appended.

3. Visual aid reinforcing proper VIVITROL injection technique (Key Techniques to Reduce Severe Injection Site Reactions poster)

Alkermes will provide healthcare providers with a *Key Techniques to Reduce Severe Injection Site Reactions* poster reinforcing proper intramuscular injection procedure for VIVITROL. Alkermes will request that healthcare providers hang this poster in the area in which VIVITROL injections are administered.

This *Key Techniques to Reduce Severe Injection Site Reactions* poster will be distributed beginning within 60 days of the modified REMS approval date, (July 29, 2013) with the *DHCP Letter*. It will be distributed by the sales force to each healthcare provider upon whom they call and it will be available on the VIVITROL REMS website (www.vivitrolrems.com) for 3 years following approval of the modified VIVITROL REMS, (July 29, 2013).

The *Key Techniques to Reduce Severe Injection Site Reactions* poster is appended.

4. VIVITROL REMS Website

Within 30 days of the modified REMS approval, (July 29, 2013), Alkermes will post information for healthcare providers and patients on the new VIVITROL REMS website

(www.vivitrolrems.com). This information will be available on the website for 3 years following approval of the modified VIVITROL REMS, (July 29, 2013).

The content of the web-based material will include the following:

- Goals of the REMS
- Medication Guide for VIVITROL
- Prescribing Information for VIVITROL
- *Dear Healthcare Provider (DHCP) Letter*
- *VIVITROL Patient Counseling Tool*
- *Key Techniques to Reduce Severe Injection Site Reactions* poster

The web-based material is appended.

C. Timetable for Submission of Assessments

Alkermes will submit REMS Assessments to FDA 2 years, 4 years and 7 years from the date of the approval of the modified REMS, (July 29, 2013). To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 days before the submission date for that assessment.

Alkermes will submit each assessment so it will be received by the FDA on or before the due date.