

**NDA 21-897**  
**VIVITROL<sup>®</sup>**  
**(naltrexone for extended-release injectable suspension)**  
**Injection**  
**Opioid Antagonist**

**Alkermes, Inc.**  
**852 Winter Street**  
**Waltham, MA 02451**  
**1-800-848-4876**

**RISK EVALUATION AND MITIGATION STRATEGY (REMS)**

**I. GOALS**

The goal of this REMS is to inform patients about the serious risks associated with the use of VIVITROL (naltrexone for extended-release injectable).

**II. REMS ELEMENTS**

**A. Medication Guide**

Alkermes will ensure a currently approved Medication Guide will be dispensed with each VIVITROL (naltrexone for extended-release injectable) prescription in accordance with 21 CFR 208.24.

VIVITROL is packaged as a single unit of use. One Medication Guide will be available in each carton of VIVITROL to assure that a copy will be available for distribution to patients using the product.

Because the Medication Guide is included as part of the packaging for VIVITROL, Alkermes has met the requirements of 21 CFR 208.24 for distribution and dispensing of the Medication Guide.

Alkermes will include a statement on the carton/container label of each package of VIVITROL instructing the authorized dispenser to provide a copy of the Medication Guide each time a prescription of VIVITROL is dispensed.

A copy of the [Medication Guide](#) is appended to the REMS document.

**B. Timetable for Submission of Assessments**

Alkermes will submit REMS Assessments to FDA 18 months, 3 years and 7 years from the date of the approval of REMS. 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.

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21897	SUPPL-10	ALKERMES INC	VIVITROL (NALTREXONE LONG ACTING INJECTI
NDA-21897	SUPPL-5	ALKERMES INC	VIVITROL (NALTREXONE LONG ACTING INJECTI

---

**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

---

/s/

---

LARISSA LAPTEVA  
03/22/2010