# Provider Locator Agreement—Retail Pharmacy & Retail Clinic Injection Providers

Vivitrol2gether℠ With you along the way

Vivitrol® (naltrexone for extended-release injectable suspension)

## TERMS OF PARTICIPATION – Retail Pharmacy Injection Provider/Retail Clinic Injection Provider

Your name, address and other information that you provide to us will be used by Alkermes, Inc. ("Alkermes") and the companies working with Alkermes to provide VIVITROL® (naltrexone for extended-release injectable suspension) patient services, pursuant to which your information may be made available to other Healthcare Providers, patients, and consumers who wish to access your services as a Retail Pharmacy Injection Provider or Retail Clinic Injection Provider. To be included in the VIVITROL Provider Locator as a Retail Pharmacy Injection Provider/Retail Clinic Injection Provider, you must be validly licensed (as required by state or federal law) and meet all of the following criteria for: **Retail Pharmacy Injection Provider/Retail Clinic Injection Provider**: (A) Experienced in reconstituting and injecting VIVITROL in accordance with the FDA-approved product labeling (B) Willing and able to accept VIVITROL product from a Dispensing Pharmacy for administration by a healthcare provider, provided the Dispensing Pharmacy meets the requirements of the Retail Pharmacy Injection Provider/Retail Clinic Injection Provider (C) Accepting patient referrals for injection of VIVITROL, provided they meet the requirements of the Retail Pharmacy Injection Provider/Retail Clinic Injection Provider (D) Able to administer VIVITROL injection in a private room or private area within your site of care.

You acknowledge that you have received, read and understood the full Prescribing Information for VIVITROL, including the directions for administration and use of the product. You are fully and solely responsible for the quality of care to be provided at your site of care.

We may contact you by e-mail, postal mail or telephone to verify and update your profile, notify you as to any changes in eligibility criteria, and assess your continued eligibility for the Provider Locator.

Alkermes will not share your information with anyone else except as described above or as required by law. Inclusion of your name and organizational information as part of our Vivitrol2gether℠ Patient Support Services does not represent, and will not necessarily result in, any endorsement, referral or recommendation by Alkermes or Vivitrol2gether Patient Support Services and your agreement to be listed in the Provider Locator shall not be construed as an inducement or encouragement for the referral of patients or use of particular products. If you want your organization or any of your sites removed from the Provider Locator, please contact Vivitrol2gether Patient Support Services at 1-800-VIVITROL (1-800-848-4876).

## PRIMARY PROVIDER/FACILITY

Legal name of provider/facility _____

Type of facility:

☐Retail Pharmacy Injection Provider

☐Retail Clinic Injection Provider

Phone _____ Fax _____ Email _____

Address _____ City _____ State _____ ZIP _____

Name of responsible party at the above provider/facility _____

**By signing below, I hereby certify that I have read, understood and agree to comply with the terms of participation set forth above.**

**If at any time Alkermes determines the applicable Healthcare Provider criteria are not met, Alkermes may at its sole discretion remove the Retail Pharmacy Injection Provider/Retail Clinic Injection Provider and any additional Retail Pharmacy Injection Provider/Retail Clinic Injection Provider facility sites from this program. The undersigned is the above-named provider, or if I am signing on behalf of a facility, I certify that I am authorized to do so.**

Name/Title (please print)_____

**Signature** _____ **Date of Signature** _____

Alkermes reserves the right to alter or discontinue this program at our discretion.

**Additional Retail Pharmacy Injection Provider/Retail Clinic Injection Provider Sites**
To list additional Retail Pharmacy Injection Provider/Retail Clinic Injection Provider sites on the Provider Locator, subject to the Terms of Participation of this Agreement, complete the required information on page 2 for each site and FAX this completed form to 1-781-207-8540. You agree that this additional Retail Pharmacy Injection Provider/Retail Clinic Injection Provider information may be made available to other Healthcare Providers, patients, and consumers who wish to access your Retail Pharmacy Injection Provider/Retail Clinic Injection Provider services.

→ **Please return this form via fax to: 1-781-207-8540 or call 1-800-848-4876 with any questions.**

**PLEASE SEE IMPORTANT SAFETY INFORMATION ON PAGE 3. PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE, OR VISIT VIVITROL.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.**

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## ADDITIONAL PROVIDER SITES

Please list all additional provider sites. If preferred, you may attach a spreadsheet with the following fields provided for each location.

| Name of provider/facility | Address (street, city, state, ZIP) | Phone | Fax | DEA # | NPI # |
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# Provider Locator Agreement—Retail Pharmacy & Retail Clinic Injection Providers

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## IMPORTANT SAFETY INFORMATION FOR VIVITROL® (NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION)

### INDICATIONS

**VIVITROL is indicated for:**

- Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- Prevention of relapse to opioid dependence, following opioid detoxification.
- VIVITROL should be part of a comprehensive management program that includes psychosocial support.

### CONTRAINDICATIONS

**VIVITROL is contraindicated in patients:**

- Receiving opioid analgesics
- With current physiologic opioid dependence
- In acute opioid withdrawal
- Who have failed the naloxone challenge test or have a positive urine screen for opioids
- Who have exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent

### WARNINGS AND PRECAUTIONS

**Vulnerability to Opioid Overdose:**

- After opioid detoxification, patients are likely to have a reduced tolerance to opioids. VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration. As the blockade wanes and eventually dissipates completely, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc.).
- Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment. Patients and caregivers should be told of this increased sensitivity to opioids and the risk of overdose. Discuss the availability of naloxone for the emergency treatment of opioid overdose with the patient and caregiver, at the initial VIVITROL injection and with each subsequent injection. Strongly consider prescribing naloxone for the emergency treatment of opioid overdose.
- Although VIVITROL is a potent antagonist with a prolonged pharmacological effect, the blockade produced by VIVITROL is surmountable. The plasma concentration of exogenous opioids attained immediately following their acute administration may be sufficient to overcome the competitive receptor blockade. This poses a potential risk to individuals who attempt, on their own, to overcome the blockade by administering large amounts of exogenous opioids.
- Any attempt by a patient to overcome the VIVITROL blockade by taking opioids may lead to fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.

**Injection Site Reactions:**

- VIVITROL must be prepared and administered by a healthcare provider.
- VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe.
- In the clinical trials, one patient developed an area of induration that continued to enlarge after 4 weeks, with subsequent development of necrotic tissue that required surgical excision.
- Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention.
- Inadvertent subcutaneous/adipose layer injection of VIVITROL may increase the likelihood of severe injection site reactions.
- Select proper needle size for patient body habitus, and use only the needles provided in the carton.
- Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

**Precipitation of Opioid Withdrawal:**

- When withdrawal is precipitated abruptly by administration of an opioid antagonist to an opioid-dependent patient, the resulting withdrawal syndrome can be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization, and in some cases, management in the ICU.
- To prevent occurrence of precipitated withdrawal, opioid-dependent patients, including those being treated for alcohol dependence, should be opioid-free (including tramadol) before starting VIVITROL treatment:
  - An opioid-free interval of a minimum of 7–10 days is recommended for patients previously dependent on short-acting opioids.
  - Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two weeks.
- If a more rapid transition from agonist to antagonist therapy is deemed necessary and appropriate by the healthcare provider, monitor the patient closely in an appropriate medical setting where precipitated withdrawal can be managed.
- Patients should be made aware of the risk associated with precipitated withdrawal and be encouraged to give an accurate account of last opioid use.
- Precipitated opioid withdrawal has been observed in alcohol-dependent patients in circumstances where the prescriber had been unaware of the additional use of opioids or co-dependence on opioids.

**Hepatotoxicity:**

- Cases of hepatitis and clinically significant liver dysfunction have been observed in association with VIVITROL. Warn patients of the risk of hepatic injury; advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue use of VIVITROL in patients who exhibit acute hepatitis symptoms.

**Depression and Suicidality:**

- Alcohol- and opioid-dependent patients taking VIVITROL should be monitored for depression or suicidal thoughts. Alert families and caregivers to monitor and report the emergence of symptoms of depression or suicidality.

**When Reversal of VIVITROL Blockade Is Required for Pain Management:**

- For VIVITROL patients in emergency situations, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required to reverse the VIVITROL blockade, patients should be closely monitored by trained personnel in a setting staffed and equipped for CPR.

**Eosinophilic Pneumonia:**

- Patients who develop dyspnea and hypoxemia should seek medical attention immediately. Consider the possibility of eosinophilic pneumonia in patients who do not respond to antibiotics.

**Hypersensitivity Reactions including Anaphylaxis:**

- Cases of urticaria, angioedema, and anaphylaxis have been observed with the use of VIVITROL.
- Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.
- In the event of a hypersensitivity reaction, patients should be advised to seek immediate medical attention in a healthcare setting prepared to treat anaphylaxis. The patient should not receive any further treatment with VIVITROL.

**Intramuscular Injections:**

- As with any intramuscular injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

**Alcohol Withdrawal:**

- Use of VIVITROL does not eliminate nor diminish alcohol withdrawal symptoms.

**Interference with Laboratory Tests**

- VIVITROL may be cross-reactive with certain immunoassay methods for the detection of drugs of abuse (specifically opioids) in urine.
- For further information, reference to the specific immunoassay instructions is recommended.

### ADVERSE REACTIONS

- The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence (ie, those occurring in ≥5% and at least twice as frequently with VIVITROL than placebo) include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), arthralgia, arthritis, or joint stiffness, muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders.
- The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients (ie, those occurring in ≥2% and at least twice as frequently with VIVITROL than placebo) were hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

**You are encouraged to report side effects to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.**

**PLEASE SEE ACCOMPANYING PRESCRIBING INFORMATION AND MEDICATION GUIDE. REVIEW THE MEDICATION GUIDE WITH YOUR PATIENTS.**

Alkermes®


VIV-005946
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