Provider Locator Agreement

Vivitrol2gether™ With you along the way

Vivitrol® (naltrexone for extended-release injectable suspension)

TERMS OF PARTICIPATION

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. The Provider Locator lists three types of Healthcare Providers: Medical Management Providers, VIVITROL Injection Providers, and Psychosocial Counseling Providers. In some instances, a Healthcare Provider may be able to provide more than one of these services. In order to be included within the VIVITROL Provider Locator as one or more of these types of Healthcare Providers, you must be validly licensed (as required by state or federal law) and meet all of the criteria of the applicable Healthcare Provider type(s): **Medical Management Provider** (i.e., physicians, nurse practitioners, physician assistants): (A) Able and willing to write prescriptions for pharmaceutical products (B) Experienced in prescribing VIVITROL for the treatment of alcohol and/or opioid dependence (C) Accepting new patients, provided they meet the requirements of the Healthcare Provider's practice (i.e., accepted insurance types, etc.) (D) If and as necessary, willing and able to refer patients to other Healthcare Providers for injection of VIVITROL and the provision of psychosocial services. **VIVITROL Injection Provider** (i.e., physicians, licensed nurses, physician assistants): (A) Experienced in reconstituting and injecting VIVITROL in accordance with the FDA-approved product labeling (B) Accepting patient referrals for injection of VIVITROL, provided they meet the requirements of the Healthcare Provider's practice (i.e., accepted insurance types, etc.) (C) If and as necessary, willing and able to refer patients to other Healthcare Providers for the provision of psychosocial services or medical management. Psychosocial Counseling Provider (i.e., counselors): (A) Experienced in providing psychosocial support to patients treated with VIVITROL (B) Willing to accept patient referrals for the provision of psychosocial support to patients treated with VIVITROL, provided they meet the requirements of the Healthcare Provider's practice (i.e., accepted insurance types, etc.) (C) If and as necessary, willing and able to refer patients to other Healthcare Providers for medical management with VIVITROL and the injection of VIVITROL. You acknowledge that you have received, read and understood the full Prescribing Information for VIVITROL® (naltrexone for extended-release injectable suspension), 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, Inc. 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, Inc. 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 to stop receiving this information, you may ask us to remove you from our contact list by calling Vivitrol2gether℠ Patient Support Services at 1-800-VIVITROL (1-800-848-4876).

PRIMARY FACILITY

INPATIENT

☐ Treatment Center ☐ Inpatient Hospital ☐ Detox Facility ☐ Psychiatric Hospital ☐ Other (specify): _____

OUTPATIENT

☐ Private Practice ☐ Group Practice ☐ Hospital Outpatient Department ☐ Intensive Outpatient Program (IOP) ☐ Injection Clinic ☐ Clinic
☐ Community Mental Health Center (CMHC) ☐ Partial Hospitalization Program (PHP) ☐ Federally Qualified Healthcare Center (FQHC)
☐ Other (specify): _____

Name of Primary Practice/Facility _____

Phone _____ Fax _____

Address _____ City _____ State _____ Zip _____

Facility Website _____ DEA # _____ NPI # _____ ME # _____

Email _____ Best Time to Call _____

VIVITROL-related List of Services Offered (Check all that apply. See applicable criteria for Healthcare Provider types above.)

☐ Counseling ☐ Medical Management ☐ VIVITROL Injection for Your Patients ☐ VIVITROL Injection for Other Practices

Hours That Site is Available for Providing Injections: M_____ T_____ W_____ Th_____ F_____ Sat_____ Sun_____

Does this facility treat: ☐ Alcohol Dependence ☐ Opioid Dependence ☐ Both

Accepted Insurance types: ☐ Most private health plans, most public health plans ☐ Most private health plans, no public health plans
☐ Most public health plans, no private health plans ☐ Limited health plan network, please contact office for info

PRIMARY PROVIDER

Name of primary provider at the above facility _____

Does the primary provider at this facility also have a secondary facility? ☐Yes ☐No (If yes, please complete side 2 of this form.)

Are there secondary providers at the above facility? ☐Yes ☐No (If yes, please complete side 2 of this form.)

By signing the 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 remove my name and related facilities 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.

For additional providers and additional facilities, please see page 2 for more information.

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 AND FACILITY INFORMATION:

ADDITIONAL FACILITY

INPATIENT

☐ Treatment Center ☐ Inpatient Hospital ☐ Detox Facility ☐ Psychiatric Hospital ☐ Other (specify): _____

OUTPATIENT

☐ Private Practice ☐ Group Practice ☐ Hospital Outpatient Department ☐ Intensive Outpatient Program (IOP) ☐ Injection Clinic ☐ Clinic

☐ Community Mental Health Center (CMHC) ☐ Partial Hospitalization Program (PHP) ☐ Federally Qualified Healthcare Center (FQHC)

☐ Other (specify): _____

Name of Primary Practice/Facility _____

Phone _____ Fax _____

Address _____ City _____ State _____ Zip _____

Facility Website _____ DEA # _____ NPI # _____ ME # _____

Email _____ Best Time to Call _____

VIVITROL-related List of Services Offered (check all that apply)

☐ Counseling ☐ Medical Management ☐ VIVITROL Injection for Your Patients ☐ VIVITROL Injection for Other Practices

Hours That Site is Available for Providing Injections: M_____ T_____ W_____ Th_____ F_____ Sat_____ Sun_____

Do you have experience injecting VIVITROL? ☐Yes ☐No Will You Accept Buy and Bill? ☐Yes ☐No

Does this facility treat: ☐ Alcohol Dependence ☐ Opioid Dependence ☐ Both

Is your practice accepting new patients for alcohol and opioid dependence treatment? ☐Yes ☐No

ADDITIONAL PROVIDER 1

Name of secondary provider _____

Facility name of secondary provider _____

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

ADDITIONAL PROVIDER 2

Name of secondary provider _____

Facility name of secondary provider _____

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

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

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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.
- 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 injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe.
- 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.

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:

- Cases of eosinophilic pneumonia requiring hospitalization have been reported. Warn patients of the risk of eosinophilic pneumonia and to seek medical attention if they develop symptoms of pneumonia.

Hypersensitivity Reactions:

- Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.

Intramuscular Injections:

- As with any IM 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.

ADVERSE REACTIONS

- Serious adverse reactions that may be associated with VIVITROL therapy in clinical use include severe injection site reactions, eosinophilic pneumonia, serious allergic reactions, unintended precipitation of opioid withdrawal, accidental opioid overdose, and depression and suicidality.
- 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), 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®

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