02179892

Patient Assistance Program

Vivitrol2gether™ With you along the way | Vivitrol® (naltrexone for extended-release injectable suspension)

COMPLETE ALL FIELDS TO AVOID PROCESSING DELAYS. PRESCRIPTION ONLY VALID IF FAXED. FAX COMPLETED FORM TO: 1-800-848-7628

QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876).
The Patient Assistance Program for VIVITROL hours are 9 AM-8 PM (EST)

ADMITTANCE DATE: _____ ESTIMATED DISCHARGE DATE: _____

1. PRESCRIBER OR FACILITY INFORMATION

Prescriber Name*

State License # DEA #

Prescriber Phone # NPI #

Facility Name Fax #

Address

City State Zip Code

Staff Contact Name

Staff Contact Phone #

Staff Contact E-mail

2. PATIENT INFORMATION

Name (First) (Middle Initial) (Last)

Last 4 digits of SSN Date of Birth

Gender ☐ Male ☐ Female ☐ _____

Address

City State Zip Code

Phone Instructions (Best Day, Time, and Number)

E-mail Address

→ INSTRUCT PATIENT TO LIST ALTERNATE CONTACTS ON PAGE 2.

4. PATIENT ASSISTANCE PROGRAM

☐ **Check here if you would like to be assessed for the Patient Assistance Program.**

I am a US Resident. ☐ Yes ☐ No

FINANCIAL INFORMATION
(ALL VALUES SHOULD REFLECT YEARLY AMOUNTS FOR ENTIRE HOUSEHOLD)

Total Gross Yearly Income: _____

☐ Attached is a copy of my most recent federal tax return

Household Size: _____
(Number of people who contribute to or are dependent on your household income.)

☐ I do not file federal taxes
(Additional follow up or documentation may be required for patients who do not file taxes.)

☐ I understand that to qualify for the Patient Assistance Program, my household income and household size must meet program requirements. I certify that my household size and household income, provided above, are accurate, as is my income documentation. I understand that my eligibility will be based on additional program requirements and, if approved, I must continue to meet eligibility requirements on an ongoing basis as defined by the program in order to receive benefits. Subject to continuing eligibility, patients will be approved for 6 months for a maximum of 6 cartons. Patients requiring assistance beyond 6 months will be required to reapply for continued program eligibility. I certify that I will notify the Patient Assistance Program at 1-800-848-4876 if my income or health insurance status changes in order to reassess my eligibility. I understand that if I am no longer eligible I will be removed from the program.

☐ I am not enrolled in, or covered by, Medicare nor am I in a residential correctional program.

Your application may be subject to audit or request for additional documentation.

Patient's Signature X _____

Date of Signature _____ **Phone #** _____

3. PATIENT DIAGNOSIS—Please complete the diagnosis code(s) you would like to use by filling in the additional digits.

(A list of codes can be found on page 3, section 8)

Alcohol Dependence ICD-10	Opioid Dependence ICD-10
F10. _____	F11. _____
F10. _____	F11. _____
F10. _____	F11. _____
F10. _____	F11. _____
F10. _____	F11. _____

Patient has tried and failed the following medication(s):

_____

Please list any known allergies to medications or other substances:

_____

Patient's concurrent medication:

_____

5. PRESCRIPTION INFORMATION AND ATTESTATION — *PRESCRIBER SIGNATURE MUST BE THE SAME AS THE PRESCRIBER NAME ABOVE

Patient Name

VIVITROL 380 mg x 1 unit inject 380 mg IM every 4 weeks or every 1 month Provider State License #

Refill _____ times (Complete refills to minimize interruption in monthly VIVITROL therapy)

By signing below, I verify that the information provided in this Vivitrol2gether enrollment form is complete and accurate to the best of my knowledge. I understand that Alkermes, Inc., reserves the right at any time and for any reason, without notice, to modify this Vivitrol2gether enrollment form or to modify or discontinue any services or assistance provided through Vivitrol2gether. Finally, I authorize Alkermes, its affiliates, representatives and agents as my designated agents to use and disclose my patient's health information as necessary to verify the accuracy of any information provided, to provide reimbursement services through Vivitrol2gether, to forward the above prescription, by fax or other mode of delivery, to a pharmacy for fulfillment, and (as applicable) to assess my patient's eligibility for co-pay assistance.

☐ I hereby attest that, to the best of my information and knowledge, the above named patient is not eligible to access VIVITROL treatment through any State or Federal program or any other public or private means (including any grant programs), and is not in a residential correctional program.

Prescriber's Signature X _____ (if applicable) Prescriber's Signature (no stamps allowed)

X _____ Dispense as Written

X _____ Substitution Permitted

Date of Signature _____

Patient Assistance Program

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PATIENTS SHOULD COMPLETE ALL FIELDS ON THIS PAGE.

QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876).
The Patient Assistance Program for VIVITROL hours are 9 AM-8 PM (EST)

6. ALTERNATE PATIENT CONTACT(S)

By signing below, I authorize my Contact(s), listed below, to receive logistical and administrative information related to my treatment, such as appointment reminders, and to make decisions on my behalf—for which I will remain liable—regarding delivery of VIVITROL® (naltrexone for extended-release injectable suspension). Alkermes is not liable for any decision(s) made by the Contact(s) or actions taken in reliance on such Contact(s) decisions.

Please list any Contacts authorized as set forth above:

Designee Name (1)	Relationship	Phone #	☐ Home ☐ Mobile ☐ Work
Designee Name (2)	**Relationship**	**Phone #**	☐ Home ☐ Mobile ☐ Work
Patient's Signature X		**Date of Signature**	

7. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION

By signing and printing my name below, I authorize: 1. my prescribing healthcare provider, **2.** the healthcare provider who will administer VIVITROL to me, **3.** the pharmacy(ies) to which my VIVITROL prescription is sent for fulfillment (the "Pharmacy"), and **4.** my health plans and insurers (collectively, my "Healthcare Entities") to use and disclose to: **1.** Alkermes, Inc. and the companies working with Alkermes, Inc. to provide the VIVITROL patient support services I request, which are United BioSource Corporation, IQVIA, Inc., AllCare Plus Pharmacy, Inc. (collectively, "Alkermes") and **2.** my Contact(s) listed above (together with Alkermes, the "Recipients") health information related to my medical condition, including information about my drug or alcohol addiction, my mental health condition(s), my treatment with VIVITROL, my insurance coverage, as well as the information requested in this form (taken together, "Information") **for the specific purposes** of allowing Alkermes to facilitate: **1.** ordering, delivering and administering VIVITROL, **2.** conducting reimbursement verification and obtaining payment from my health plan(s) and insurer(s), **3.** providing me with educational and therapy support services by mail, text-messaging, e-mail, and/or telephone, which may include sending me product information materials and treatment reminders, and motivational messages, **4.** referring me to, or determining my eligibility for, other programs, foundations or alternative sources of funding or coverage to help me with the costs of VIVITROL and **5.** reviewing and analyzing fulfillment of VIVITROL prescriptions. **Information May Be Further Disclosed:** I understand that Information disclosed pursuant to this authorization could be re-disclosed by a Recipient and may no longer be protected by federal privacy law (HIPAA).

I understand that signing this authorization is voluntary and if I do not sign this authorization it will not affect my ability to obtain treatment, insurance or insurance benefits from my Healthcare Entities. I understand, however, that if I do not sign this authorization, I will not be eligible to receive the educational, patient support or other services described above, which are being provided by, or on behalf of, Alkermes. I will consult with my healthcare provider before making any treatment decisions. I understand I have the right to receive a copy of this authorization after I sign. I understand that the Pharmacy may receive payment from Alkermes, Inc. in exchange for Information.

I may withdraw this authorization at any time by mailing or faxing a written request to Vivitrol2gether™, 852 Winter Street, Waltham, MA 02451. Withdrawal of this authorization will end my consent to further disclosures of information authorized herein by my Healthcare Entities when they receive notice of my withdrawal, but will not affect previous disclosures and uses pursuant to this authorization or as permitted by applicable law. This authorization expires on the earlier of **(1)** five years from the date of signature below or **(2)** the maximum period permitted by applicable state law, unless I withdraw it earlier as set forth above.

Patient's Signature X	Print Name x	Date of Signature
Guardian/Legal Representative's Signature† X		**Authority/Relationship to Patient**

† If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required.

Patient Assistance Program

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PATIENTS SHOULD COMPLETE ALL FIELDS ON THIS PAGE.

QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876).
The Patient Assistance Program for VIVITROL hours are 8 AM-8 PM (EST)

8. PATIENT DIAGNOSIS CODES

Alcohol Dependence:

(ICD-10)	
F10.2	Alcohol dependence
- F10.20	Uncomplicated
- F10.21	In remission
- F10.22	Alcohol dependence with intoxication
- F10.220	Uncomplicated
- F10.221	Delirium
- F10.229	Unspecified
F10.23	Alcohol dependence with withdrawal
- F10.230	Uncomplicated
- F10.231	Delirium
- F10.232	With perceptual disturbance
- F10.239	Unspecified
F10.24	With alcohol-induced mood disorder
F10.25	Alcohol dependence with alcohol-induced psychotic disorder
- F10.250	With delusions
- F10.251	With hallucinations
- F10.259	Unspecified
F10.26	With alcohol-induced persisting amnestic disorder
F10.27	With alcohol-induced persisting dementia
F10.28	Alcohol dependence with other alcohol-induced disorders
- F10.280	Alcohol dependence with alcohol-induced anxiety disorder
- F10.281	Alcohol dependence with alcohol-induced sexual dysfunction
- F10.282	Alcohol dependence with alcohol-induced sleep disorder
- F10.288	Alcohol dependence with other alcohol-induced disorder
F10.29	With unspecified alcohol-induced disorder

Opioid Dependence:

(ICD-10)	
F11.2	Opioid dependence
- F11.20	Uncomplicated
F11.21	In remission
F11.22	Opioid dependence with intoxication
- F11.220	Uncomplicated
- F11.221	Delirium
- F11.222	With perceptual disturbance
- F11.229	Unspecified
F11.23	With withdrawal
F11.24	With opioid-induced mood disorder
F11.25	Opioid dependence with opioid-induced psychotic disorder
- F11.250	With delusions
- F11.251	With hallucinations
- F11.259	Unspecified
F11.28	Opioid dependence with other opioid-induced disorder
- F11.281	Opioid dependence with other opioid-induced sexual dysfunction
- F11.282	Opioid dependence with other opioid-induced sleep disorder
- F11.288	Opioid dependence with other opioid-induced disorder
F11.29	With unspecified opioid-induced disorder

Patient Assistance Program

Vivitrol2gether™ With you along the way

Vivitrol® (naltrexone for extended-release injectable suspension)

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 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.
- 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 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.

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 ALSO SEE ACCOMPANYING PRESCRIBING INFORMATION AND MEDICATION GUIDE. REVIEW MEDICATION GUIDE WITH YOUR PATIENTS.

Alkermes®

VIV-004878 Printed in the U.S.A.

Patient Enrollment Form

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COMPLETE ALL FIELDS TO AVOID PROCESSING DELAYS.
PRESCRIPTION ONLY VALID IF FAXED.
FAX COMPLETED FORM TO: 1-877-339-8484.
QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876), 8AM–8PM (EST).

Prescriber Signature(s) (page 1) and Patient Signature(s) (page 2) required.

1. PLEASE SELECT PROGRAM OFFERING(S) THAT BEST MEET(S) YOUR PATIENT'S NEEDS

- ☐ Vivitrol2gether sends prescription to pharmacy*
- ☐ VivitrolNow℠/Buy and Bill*
- ☐ Transition of Care Services
- ☐ Refill Reminders
- ☐ Benefits Verification

*Includes Transition of Care, Refill Reminders and Benefits Verification as applicable

2. PRESCRIBER OR FACILITY INFORMATION

Prescriber
(First) (Last)
Tax ID # State License #
NPI #
Facility Name
Facility Phone # Fax #
Address
City State ZIP Code
Staff Contact Name
Staff Contact Phone #
Staff Contact E-mail

3. PATIENT INFORMATION

Admittance Date Estimated Discharge Date
Name
(First) (Middle Initial) (Last)
Date of Birth Gender ☐ Male ☐ Female ☐ _____
Address
City State ZIP Code
Home Phone # Mobile Phone #
Phone Instructions (Best Day, Time, and Number)

E-mail Address

→ *INSTRUCT PATIENT TO LIST ALTERNATE CONTACTS ON PAGE 2.*

4. PATIENT DIAGNOSIS—(A list of codes can be found on page 3, section 13)

Please check primary diagnosis
☐ Alcohol Dependence ☐ Opioid Dependence

ICD-10	ICD-10
F10. _____	F11. _____
F10. _____	F11. _____
F10. _____	F11. _____
F10. _____	F11. _____
F10. _____	F11. _____

Patient has tried and failed the following medication(s):

Please list any known allergies to medications or other substances:

Patient's concurrent medications:

5. TRANSITION OF CARE COORDINATION

Patient needs VIVITROL by (date) ____/____/____
Preferred pharmacy (optional) Phone #
Special shipping instructions

Please select one
- ☐ Patient will receive future injections at this site.
- ☐ Patient will transition to provider below for future injections.

Provider Name Phone #
Provider Address

- ☐ Patient requires assistance from Vivitrol2gether to locate new provider for future injections.

See Section 12 Injection Provider/Specialty Pharmacy Selection Information.

6. PATIENT INSURANCE INFORMATION

A. Payment Method ☐ Insured ☐ Paying out-of-pocket

B. ATTACH COPY OF PATIENT'S MEDICAL AND PHARMACY INSURANCE CARDS (BOTH SIDES)

C. IF YOU DO NOT ATTACH INSURANCE CARD, COMPLETE SECTION BELOW.

Insurance Type ☐ Commercial ☐ Medicaid ☐ Medicare ☐ Other
Insurance Name
Policyholder Name PA # (If obtained)
Relationship to Patient Insurance Phone #
Policyholder Employer Name
Policy # Group ID #

PHARMACY BENEFIT PLAN (PBM)
PBM Name PBM Phone #
Member Name Member #
Relationship to Patient
Member Employer Name
Rx Group # Rx BIN # Rx PCN #
Co-pay Card Number (If obtained)

7. PRESCRIPTION INFORMATION

Not required for patient transition support from hospital setting

Patient Name _____
(Required - Please Print Full Name)

VIVITROL 380 mg x 1 unit inject 380 mg IM every 4 weeks or every 1 month

Provider State License # Refill _____ times
(Complete refills to minimize interruption in monthly VIVITROL therapy)

By signing below, I certify that the therapy above is medically necessary. I authorize Alkermes, its affiliates, representatives and agents as my designated agents to forward the prescription, by fax or other mode of delivery, to a pharmacy for fulfillment.

Dispense as Written
OR Prescriber Signature' Date

Substitution Permitted
Prescriber Signature' Date

'Prescriber Signature must be the same as the Prescriber Name

8. PRESCRIBER ATTESTATION

By signing below, I verify that the information provided in this Vivitrol2gether enrollment form is complete and accurate to the best of my knowledge. I understand that Alkermes, Inc., reserves the right at any time and for any reason, without notice, to modify this Vivitrol2gether enrollment form or to modify or discontinue any services or assistance provided through Vivitrol2gether. Finally, I authorize Alkermes, its affiliates, representatives and agents as my designated agents to use and disclose my patient's health information as necessary to verify the accuracy of any information provided, to provide reimbursement services through Vivitrol2gether and (as applicable) to assess my patient's eligibility for co-pay assistance.

Prescriber Signature X Date

Patient Enrollment Form

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QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876), 8AM–8PM (EST).

9. ALTERNATE PATIENT CONTACT(S)

By signing below, I authorize my Contact(s), listed below, to receive logistical and administrative information related to my treatment, such as appointment reminders, and to make decisions on my behalf—for which I will remain liable—regarding delivery of VIVITROL® (naltrexone for extended-release injectable suspension). Alkermes is not liable for any decision(s) made by the Contact(s) or actions taken in reliance on such Contact(s) decisions.

Please list any Contacts authorized as set forth above:

Designee Name (1)	Relationship	Phone #	☐ Home ☐ Mobile ☐ Work
Designee Name (2)	**Relationship**	**Phone #**	☐ Home ☐ Mobile ☐ Work

Patient's Signature X **Date**

10. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION

By signing and printing my name below, I authorize: 1. my prescribing healthcare provider, **2.** the healthcare provider who will administer VIVITROL to me, **3.** the pharmacy(ies) to which my VIVITROL prescription is sent for fulfillment (the "Pharmacy"), and **4.** my health plans and insurers (collectively, my "Healthcare Entities") to use and disclose to: **1.** Alkermes, Inc. and the companies working with Alkermes, Inc. to provide the VIVITROL patient support services I request, which are United BioSource Corporation, IQVIA, Inc., (collectively, "Alkermes") and **2.** my Contact(s) listed above (together with Alkermes, the "Recipients") health information related to my medical condition, including information about my drug or alcohol addiction, my mental health condition(s), my treatment with VIVITROL, my insurance coverage, as well as the information requested in this form (taken together, "Information") **for the specific purposes** of allowing Alkermes to facilitate: **1.** ordering, delivering and administering VIVITROL, **2.** conducting reimbursement verification and obtaining payment from my health plan(s) and insurer(s), **3.** providing me with educational and therapy support services by mail, text-messaging, e-mail, and/or telephone, which may include sending me product information materials, treatment reminders, and motivational messages, **4.** referring me to, or determining my eligibility for, other programs, foundations or alternative sources of funding or coverage to help me with the costs of VIVITROL and **5.** reviewing and analyzing fulfillment of VIVITROL prescriptions. **Information May Be Further Disclosed:** I understand that Information disclosed pursuant to this authorization could be re-disclosed by a Recipient and may no longer be protected by federal privacy law (HIPAA).

I understand that signing this authorization is voluntary and if I do not sign this authorization it will not affect my ability to obtain treatment, insurance or insurance benefits from my Healthcare Entities. I understand, however, that if I do not sign this authorization, I will not be eligible to receive the educational, patient support or other services described above, which are being provided by, or on behalf of, Alkermes. I will consult with my healthcare provider before making any treatment decisions. I understand I have the right to receive a copy of this authorization after I sign. I understand that the Pharmacy may receive payment from Alkermes, Inc. in exchange for Information.

I may withdraw this authorization at any time by mailing or faxing a written request to Vivitrol2gether, 852 Winter Street, Waltham, MA 02451, 1-877-329-8484. Withdrawal of this authorization will end my consent to further disclosures of Information authorized herein by my Healthcare Entities when they receive notice of my withdrawal, but will not affect previous disclosures and uses pursuant to this authorization or as permitted by applicable law. This authorization expires on the earlier of **(1)** five years from the date of signature below or **(2)** the maximum period permitted by applicable state law, unless I withdraw it earlier as set forth above.

Patient's Signature X **Print Name** **Date**

Guardian/Legal Representative Signature[1] X **Authority/Relationship to Patient**

[1]If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required.

11. CO-PAY SAVINGS PROGRAM INFORMATION FOR ELIGIBLE PATIENTS

By signing below, I certify that: I am at least 18 years old, and I am being treated for opioid dependence or alcohol dependence.

I am not enrolled in, or covered by, any local, state, federal or other government program that pays for any portion of medication costs, including but not limited to:

- Medicare, including Medicare Part D and Medicare Advantage plans
- Medicaid, including Medicaid Managed Care and Alternative Benefit Plans ("ABPs") under the Affordable Care Act
- Medigap
- Department of Defense ("DoD")
- TRICARE
- Residential Correctional Program
- Veterans Administration ("VA")

If my insurance changes, I will promptly notify Vivitrol2gether at 800-848-4876 in order to confirm my continued eligibility.

I understand the eligibility requirements described above.

Patient's Signature X **Date**

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12. INJECTION PROVIDER/SPECIALTY PHARMACY SELECTION INFORMATION (AS APPLICABLE)

If you have requested injection services for your patient, Vivitrol2gether will identify several injectors based on geographic proximity to your patient's address listed on the enrollment form (from closest to farthest from such address).

These injection providers are listed on the VIVITROL Provider Locator at VIVITROL.com. Participation on the Provider Locator is free of charge and based solely on providers' responses and does not imply a referral, recommendation or endorsement by Alkermes.

Upon request, these options will be provided to you for your patient. We will also contact the selected injection services provider to help coordinate injection services.

Upon request, prescriptions of patients enrolled in Vivitrol2gether are routed to qualified pharmacies based on insurance plan requirements, provider selection, patient preference and information obtained by Alkermes on pharmacy fulfillment for VIVITROL prescriptions covered by the insurer. Participation is free of charge. Interested pharmacies may contact 1-800-VIVITROL (1-800-848-4876).

13. PATIENT DIAGNOSIS CODES

Alcohol Dependence:

(ICD-10)	
F10.2	Alcohol dependence
- F10.20	Uncomplicated
- F10.21	In remission
- F10.22	Alcohol dependence with intoxication
- F10.220	Uncomplicated
- F10.221	Delirium
- F10.229	Unspecified
F10.23	Alcohol dependence with withdrawal
- F10.230	Uncomplicated
- F10.231	Delirium
- F10.232	With perceptual disturbance
- F10.239	Unspecified
F10.24	With alcohol-induced mood disorder
F10.25	Alcohol dependence with alcohol-induced psychotic disorder
- F10.250	With delusions
- F10.251	With hallucinations
- F10.259	Unspecified
F10.26	With alcohol-induced persisting amnestic disorder
F10.27	With alcohol-induced persisting dementia
F10.28	Alcohol dependence with other alcohol-induced disorders
- F10.280	Alcohol dependence with alcohol-induced anxiety disorder
- F10.281	Alcohol dependence with alcohol-induced sexual dysfunction
- F10.282	Alcohol dependence with alcohol-induced sleep disorder
- F10.288	Alcohol dependence with other alcohol-induced disorder
F10.29	With unspecified alcohol-induced disorder

Opioid Dependence:

(ICD-10)	
F11.2	Opioid dependence
- F11.20	Uncomplicated
F11.21	In remission
F11.22	Opioid dependence with intoxication
- F11.220	Uncomplicated
- F11.221	Delirium
- F11.222	With perceptual disturbance
- F11.229	Unspecified
F11.23	With withdrawal
F11.24	With opioid-induced mood disorder
F11.25	Opioid dependence with opioid-induced psychotic disorder
- F11.250	With delusions
- F11.251	With hallucinations
- F11.259	Unspecified
F11.28	Opioid dependence with other opioid-induced disorder
- F11.281	Opioid dependence with other opioid-induced sexual dysfunction
- F11.282	Opioid dependence with other opioid-induced sleep disorder
- F11.288	Opioid dependence with other opioid-induced disorder
F11.29	With unspecified opioid-induced disorder

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Vivitrol®
(naltrexone for extended-release injectable suspension)

IMPORTANT SAFETY INFORMATION FOR VIVITROL

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 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.
- 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 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.

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.

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