COMPLETE ALL FIELDS TO AVOID PROCESSING DELAYS. PRESCRIPTION ONLY VALID IF FAXED. **FAX COMPLETED FORM TO: 1-877-329-8484.** QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876), 9AM-8PM (EST).

Prescriber Signature(s) (section 7 & 8) and Patient Signature(s)

(section 13) required.

1. PLEASE SELECT PROGRAM OFFERING(S) THAT BEST MEET(S) YOUR PATIENT'S NEEDS				
☐ VIVITROL2GETHER*	sends prescription to pha	armacy*		
☐ Transition of Care Se	rvices*			
☐ Benefits Verification				
☐ Buy & Bill Benefits Ve	erification			
*May include Transition of Ca applicable.	are, Appointment Reminders,	and Benefits Verification as		
2. PRESCRIBER OR	FACILITY INFORMAT	TION		
Prescriber				
(First)		(Last)		
Tax ID #	State Lice	ense #		
NPI#	PTAN #			
Facility Name				
Facility Phone #	Fa	x #		
Address				
City	State	ZIP Code		
Staff Name	Staff Phor	ne #		
Staff Email Address				
Additional Information				
3. PATIENT INFORM	IATION			
Name				
(First)	(Middle Initial)	(Last)		
Date of Birth	Gender 🗌 Male	☐ Female ☐		
Address				
City	State	ZIP Code		
Mobile Phone #	Home Phone #			
Phone Instructions (Be	st Number)			
Email Address		<del></del> -		
→ INSTRUCT PATIENT TO	LIST ALTERNATE DESIGNAT	TED CONTACT(S) ON PAGE 2.		
4. PATIENT DIAGNO page 5, section 15		e codes can be found on		
Please check primary diagram Alcohol Dependence	nosis  Opioid Dependence ICD-10	Patient has tried and failed the following medication(s):		
F10	F11			
F10	F11	Please list any known allergies to medications or other substances		
F10	F11	No Known Drug Allergies (NKDA)		
F10	F11			
F10	F11	Patient's concurrent medications		



(naltrexone for extended-release injectable suspension) 380 mg/vial

5. TRANSITION OF CARE COOR	DINATION		
If the office provides all injections, sk	ip to section 6		
Patient Estimated Discharge Date (if	applicable): / /		
Select Option(s) That Apply:			
Office will provide the <b>FIRST</b> inject	on only <u>OR</u>		
	er, but injections will be administered elsewhere		
Select Option(s) That Apply:	WITDOL SCETUED to Least a service		
<ul> <li>□ Patient requires assistance from VI provider or injection site OR</li> <li>□ Patient will transition to/receive injection</li> </ul>			
Provider/Injection Site Name	Phone #		
Address			
6. PATIENT INSURANCE INFORI	MATION		
A. Payment Method ☐ Insured ☐			
B. ATTACH COPY OF PATIENT'S (1) ME (3) SECONDARY INSURANCE CARI	DICAL, (2) PHARMACY, <u>AND</u>		
C. IF YOU DO NOT ATTACH INSURANCE	CARD, COMPLETE SECTION BELOW		
Insurance Type	☐ Medicaid ☐ Medicare ☐ Other		
Insurance Name			
Policyholder Name	PA # (if obtained)		
Relationship to Patient	Insurance Phone #		
Policyholder Employer Name			
Policy #	Group ID #		
Policy Type	Other		
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(Requi	red - Please Print Full Name)		
	mg IM every 4 weeks or every 1 month		
Provider State License #	Refill times		
(Complete refills to minimize interruption i			
By signing below, I certify that the therapy above	ve is medically necessary. I authorize Alkermes, its ignated agents to forward the prescription, by fax or		
Dispense as Written	Date		
OR Prescriber Sign			
Substitution Permitted Prescriber Sign	Date		
Prescriber Sign Prescriber Signature must be the same as the			
Preferred Pharmacy Name			
Phone #	Fax#		
	nefits Verification will be run to find an		
insurance-approved pharmacy			

Patient's concurrent medications:





QUESTIONS? CALL 1-800-VIVITROL (1-800-848-4876), 9AM-8PM (EST).

#### 8. PRESCRIBER ATTESTATION

I certify that (1) I have prescribed VIVITROL® based on my professional judgment of medical necessity and that I or others in my healthcare provider group ("my Practice") will supervise the patient's medical treatment; (2) I or others in my Practice have obtained the patient's authorization to the extent required by HIPAA, the Confidentiality of Substance Use Disorder Patient Records Regulation (42 C.F.R. Part 2), or other applicable privacy laws (a) to disclose the patient information in this form to Alkermes, its agents, and service providers ("Alkermes") and (b) for Alkermes to use and disclose the information to contact the patient and to provide reimbursement support services; and (3) the information provided is accurate to the best of my knowledge.

I authorize Alkermes to act on my behalf for the limited purpose of transmitting the prescription(s) above and providing the patient information on this form to the appropriate dispensing pharmacy to the extent permitted under applicable law.

I understand the information I provide about me may be used by Alkermes to provide me with information about the VIVITROL2GETHER\* Program and Alkermes products and for analytics activities.

Prescriber's Signature X

Date

#### 9. DESIGNATED PATIENT CONTACT(S)

By signing below, I designate my Contact(s), listed below, as my personal representatives ("Designated Contact(s)") with respect to my treatment with VIVITROL, including to receive information related to my treatment with VIVITROL and make decisions on my behalf regarding delivery of VIVITROL. I authorize the pharmacy to communicate with my Designated Contact(s) in order to coordinate the delivery, receipt, storage of VIVITROL for the purpose of administration of my medication at my next scheduled appointment as applicable.

I understand that Alkermes is not liable for any decision(s) made by the Designated Contact(s) or actions taken in reliance on such Designated Contact(s) decisions.

Please list any Designated Contact(s) authorized as set forth above:

Designee Name (1)	Relationship	Phone #	Email:
Designee Name (2)	Relationship	Phone #	Email:
Patient's Signature <b>X</b>	Date		

#### 10. CO-PAY SAVINGS PROGRAM INFORMATION FOR ELIGIBLE PATIENTS

**By signing below, I certify that:** I am at least 18 years old and have commercial (private or non-governmental insurance), and have a valid prescription for a Food and Drug Administration (FDA)-approved indication.

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 have reviewed and agree to comply with the Co-pay Savings Program Terms and Conditions, including the eligibility requirements described above. For complete VIVITROL Co-Pay Savings Program Terms and Conditions, visit www.vivitrol.com

Patient's Signature X Date

#### 11. SHIPPING AUTHORIZATION FOR COMMERCIALLY INSURED PATIENTS (OPTIONAL)

If I have commercial insurance and my co-pay/coinsurance responsibility is \$0, I authorize the Fulfilling Pharmacy to communicate with my Healthcare Provider to coordinate the delivery of my VIVITROL prescription for my next scheduled appointment.

I understand that this serves as a patient authorization to ship, which means the Fulfilling Pharmacy may not contact me and/or my Designated Contact, prior to shipping VIVITROL.

Patient's Signature X Date

12. CONSENT FOR MARKETING MATERIALS AND INFORMATIONAL RESOURCES (OPTIONAL)
☐ By checking this box, I consent to receive <b>optional</b> communications and materials for marketing, market research

By checking this box, I consent to receive **optional** communications and materials for marketing, market research, or advertising purposes about products, services, and programs offered by Alkermes, its partners, and their respective affiliates at my email address below regarding the health condition selected below. I understand I am not required to provide my permission to receive marketing communications in order to participate in the VIVITROL2GETHER Program or receive my VIVITROL. I may withdraw this authorization at any time by mailing or faxing a written request to VIVITROL2GETHER, 852 Winter Street, Waltham, MA 02451, 1-800-948-7628 and this consent will remain active unless I opt out.

I am interested in receiving marketing information and resources on the following health conditions (select all that apply):			
☐ Alcohol Dependence	☐ Opioid Dependence		
Patient's Signature <b>X</b>		Date	

**Email address:** 





# 13. PATIENT AUTHORIZATION FOR USE/DISCLOSURE OF HEALTH INFORMATION (REQUIRED)

By signing below, I authorize each of my "Healthcare Providers" (eg, my physicians, pharmacists, pharmacies, other healthcare providers, and their staff) and my "Insurers" (eg, my health insurance plan listed in Section 6.) to share information about me as detailed in this Enrollment Form (my "Personal Information"). My "Personal Information" includes any and all information related to my health, including my opioid or alcohol addiction, my mental health condition, and my treatment for opioid or alcohol addiction, including treatment with VIVITROL®. My Personal Information also includes my or my Designated Contact's (see Section 9.) identifying information, contact information, my health insurance information, financial information relevant to my eligibility for VIVITROL2GETHER® Program services, and all other information described on this Enrollment Form.

I authorize my Healthcare Providers and Insurers to share my Personal Information with the following person(s) or class of person(s) (collectively "Recipients"), so they may provide the services described below:

- Alkermes, Inc., its affiliated companies, agents, and representatives (collectively, "Alkermes")
- Service providers for the VIVITROL2GETHER Program, which, as of January 2023, are United BioSource Corporation, AssistRx, Surescripts, and Datamatics Global Services, Inc., and IQVIA and its affiliates, but may be replaced with other companies providing similar services.

I authorize the Recipients to use and share my Personal Information among themselves and with my Healthcare Providers, Insurers, and Designated Contact(s) to facilitate: 1. ordering, delivering and administering VIVITROL; 2. conducting reimbursement verification and obtaining payment from my Insurer; 3. providing me with educational and therapy support services by using my provided contact information to communicate with me by mail, text message, e-mail, and/or telephone, which may include treatment reminders, information about the VIVITROL2GETHER Program and the VIVITROL Co-pay Savings Program, 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; 5. helping with my enrollment and continued participation in the VIVITROL Co-pay Savings Program in the event I am eligible for such program; and 6. conducting analysis to help Alkermes evaluate, create, and improve products and services for patients prescribed Alkermes medications.

I understand that once Personal Information is disclosed pursuant to this authorization, some of the information may not be regulated by applicable privacy regulations and could be re-disclosed, but I also understand that the Recipients do not intend to make any disclosures other than as described in this authorization. I understand that my pharmacy may receive remuneration in exchange for the use or disclosure of my Personal Information and/or any patient support services provided to me.

I understand I have the right to receive a copy of this authorization after I sign. I understand that signing this authorization is voluntary, and that if I do not sign this consent, it will not affect my ability to obtain treatment, insurance or insurance benefits. I understand, however, that if I do not sign this consent, I will not be eligible to receive the financial, educational, or other services provided by the VIVITROL2GETHER Program.

I may withdraw this authorization at any time by mailing or faxing a written request to VIVITROL2GETHER, 852 Winter Street, Waltham, MA 02451, 1-800-948-7628. Withdrawal of this authorization will not, however, invalidate disclosures and uses of my Personal Information prior to the date my notice of withdrawal is received by Alkermes.

This consent expires five (5) years from the date of my signature below unless an earlier expiration is mandatory under applicable state law.

For additional information about our privacy practices, please visit https://www.Alkermes.com/privacy-policy.

Patient's Signature X Print Name Date

Guardian/Legal Representative Signature X

Authority/Relationship to Patient

<sup>&#</sup>x27;If patient does not have capacity to act alone under state law, signature of guardian or authorized legal representative is required



**Opioid Dependence:** 



#### 14. SUPPORT LOCATIONS: A PROVIDER/INJECTION SITE OR SPECIALTY PHARMACY

For patients who require assistance finding a healthcare provider or injection site with experience administering VIVITROL®, VIVITROL2GETHER® can identify several providers and facilities based on geographic proximity to the patient address provided on this Form using the VIVITROL Provider Locator at VIVITROL.com. Inclusion in the Locator is based solely on providers' responses to Alkermes, and no fees have been paid to providers for inclusion in the Locator. Inclusion in the Locator 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. For more information, please contact 1-800-VIVITROL (1-800-848-4876).

#### 15. DIAGNOSIS CODES

The list below includes ICD-10 diagnosis codes that may be relevant for patients treated with VIVITROL\*. This list is not exhaustive and additional codes may apply. The list is provided for informational purposes only and should not be used as billing and coding advice or a coding recommendation for a specific claim.

The healthcare provider is responsible for determining the appropriate codes to accurately reflect their patient's condition, the medication and services provided to the patient, and for the representations made in the claims for reimbursement submitted on behalf of the patient.

### **Alcohol Dependence:**

- F10.221	Uncomplicated - F10.27 In remission Uncomplicated Delirium Unspecified - F10.28	persisting dementia  O Alcohol dependence with alcohol-induced	- F11.221	In remission Uncomplicated Delirium		Opioid dependence with other opioid-induced sleep disorder Opioid dependence
- F10.230 - F10.231	Uncomplicated Delirium With perceptual	with alcohol-induced sexual dysfunction		With perceptual disturbance Unspecified With withdrawal		with other opioid-induced disorder
- F10.24 - F10.250 - F10.251	Unspecified With alcohol-induced mood disorder With delusions With hallucinations Unspecified	<ul> <li>Alcohol dependence with alcohol-induced sleep disorder</li> <li>Alcohol dependence with other alcohol-induced disorder</li> </ul>	- F11.251 - F11.259	With opioid-induced mood disorder With delusions With hallucinations Unspecified Opioid dependence	- F11.29	With unspecified opioid-induced disorder
- F10.26 With alcohol-induced persisting amnestic disorder	persisting amnestic	With unspecified alcohol-induced disorder	cohol-induced o	with other opioid-induced sexual dysfunction		



Vivitrol

(naltrexone for extended-release injectable suspension) 380 mg/vial

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

#### INDICATIONS

#### **VIVITROL** is indicated for:

- The 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.
- The prevention of relapse to opioid dependence, following opioid detoxification.

VIVITROL should be part of a comprehensive management program that includes psychosocial support.

## IMPORTANT SAFETY INFORMATION

#### VIVITROL is contraindicated in patients:

- · Receiving opioid analgesics
- With current physiologic opioid dependence or 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-coglycolide (PLG), carboxymethylcellulose, or any other components of the diluent

#### **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. <u>Patients should be told</u> of the serious consequences of trying to overcome the opioid blockade.
- 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.

## **Injection Site Reactions**

- VIVITROL must be prepared and administered by a healthcare provider and must ONLY be administered as a deep intramuscular gluteal injection.
- 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.
- 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.
- 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.
- 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 a patient with opioid dependence, the resulting withdrawal syndrome can be severe. Some cases have been severe enough to require hospitalization and/or management in the ICU.

- To prevent occurrence of precipitated withdrawal, patients with opioid dependence, 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 shortacting opioids.
  - Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as 2 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, as precipitated opioid withdrawal has been observed in patients with alcohol dependence 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 and advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue VIVITROL in patients who exhibit signs and symptoms of acute hepatitis.

#### **Depression and Suicidality**

 Patients with alcohol dependence or opioid dependence 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**

 Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis, and should be advised to seek immediate medical attention in a healthcare setting prepared to treat anaphylaxis should a hypersensitivity reaction occur. 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 (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 patients with opioid dependence (occurring in ≥2% and at least twice as frequently with VIVITROL than placebo) include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

For more information about VIVITROL, please see full <u>Prescribing Information</u>.

PLEASE SEE PRESCRIBING INFORMATION AND MEDICATION GUIDE,
OR VISIT VIVITROLHCP.COM. PLEASE REVIEW MEDICATION GUIDE WITH PATIENTS.



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