

VIVITROL PROVIDER CARE PLAN

PATIENT NAME (Last, First, M.I.)	DOC NUMBER	DATE OF BIRTH	DATE OF VISIT
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INSTRUCTIONS: Please indicate date of exam/test, "A" for abnormal or "N" for normal. Insert actual results, when appropriate (e.g. lab value, weight, BP), additional explanations (PN) should be written in the patient's progress notes. See reverse side for Vivitrol treatment information

SUBJECTIVE

Symptoms of	Exam / Test Results Narrative
• Abdominal pain	
• Tremors, sweats, diarrhea or other opiate withdraw symptoms	
• Opiate craving	
Review of opiate use history	
Most recent opiate use (must be 7 days prior to Vivitrol dosing)	
Use of other sedatives (benzodiazepine)	
Compliance with AODA programming	
Other concerns of patient	

OBJECTIVE

Height/Weight/BMI	
BP/Temp/Pulse/Respirations/SAO2	
Lung/Chest exam	
Abdominal examination including liver exam	
Skin exam (jaundice)	
Neurologic/psychiatric (any s/s of withdrawal such as tremors, agitation)	

TESTS

Urine drug screen results (order if not done)	
Urine drug confirmation (if screen was positive)	
LFTs (order if not done)	
Other pertinent labs/imaging	

ASSESSMENT

Opiate Dependence	
Other substance Abuse diagnosis	
Co-morbid diseases	

RECOMMENDATIONS

Approved for Vivitrol treatment	
Not approved for Vivitrol treatment (provide reason such as active opiate use or liver disease)	

ORDERS

Vivitrol 380 mg I.M. injection once at time of discharge	
Send DOC-3763 to social work via global scan	
Print "Patient Safety Card for Emergency Opiate Use" and provide to patient at time of injection	
Order urine toxicology screen before injection to be reviewed by nurse prior to injection	

Provider reviewed Vivitrol treatment consent with patient. Patient consent signature below.

PROVIDER SIGNATURE	DATE SIGNED
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VIVITROL PRESCRIBING INFORMATION

INDICATIONS

VIVITROL is indicated for: Prevention of relapse of opioid dependence following opioid detoxification. Patient should not be using opiates at the time of initial VIVITROL administration for a minimum of 7 days. 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, poly(lactide-co-glycolide) (PLG), carboxymethylcellulose, or any other components of the diluent

WARNINGS/PRECAUTIONS

Vulnerability to Opioid Overdose: Because VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration patients are likely to have a reduced tolerance to opioids after opioid detoxification. As the blockade dissipates, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc).

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: Withdrawal precipitated by administration of VIVITROL may be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization and management in the ICU. To prevent precipitated withdrawal, patients, including those being treated for alcohol dependence:

Patient should be opioid-free (including tramadol) for a minimum of 7–10 days before starting VIVITROL.

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. Use discretion if underlying chronic liver disease.

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.

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.

VIVITROL CONSENT FOR TREATMENT

If I have previously used opioids, I may be more sensitive to lower doses of opioids and at risk of accidental overdose should I use opioids after VIVITROL treatment is discontinued. I understand it is important that I inform family members and the people closest to me of this increased sensitivity to opioids and the risk of overdose.

I understand that VIVITROL can block the effects of opioids and I will not perceive any effect if I attempt to self-administer heroin or any other opioid drug in small doses while on VIVITROL. Further, I understand that administration of large doses of heroin or any other opioid to try to bypass the blockade and get high while on VIVITROL may lead to serious injury, coma, or death.

I understand that a reaction at the site of VIVITROL injection may occur. Reactions include pain, tenderness, induration, swelling, erythema, bruising, or pruritus. Serious injection site reactions including necrosis may occur. Some of these injection site reactions have required surgery. I will seek medical attention for worsening skin reactions.

I understand that I should be off all opioids, including opioid-containing medicines, for a minimum of 7 – 10 days before starting VIVITROL in order to avoid precipitation of opioid withdrawal. I understand that withdrawal precipitated by administration of an opioid antagonist may be severe enough to require hospitalization.

I understand VIVITROL may cause liver injury. Patients should immediately notify their physician if they develop symptoms and/or signs of liver disease.

I understand may experience depression while taking VIVITROL. It is important that I inform family members and the people closest to me that I am taking VIVITROL and that I should call a doctor right away should I become depressed or experience symptoms of depression.

I understand I should carry documentation to alert medical personnel to the fact that I am taking VIVITROL (naltrexone for extended-release injectable suspension). This will help to ensure that I obtain adequate medical treatment in an emergency. I understand this documentation will be provided to me by the DOC at the time of my first injection.

I understand VIVITROL may cause an allergic pneumonia. I should immediately notify my physician if I develop signs and symptoms of pneumonia, including dyspnea, coughing, or wheezing.

I understand I may experience nausea following the initial injection of VIVITROL. These episodes of nausea tend to be mild and subside within a few days post-injection. I am less likely to experience nausea in subsequent injections. I may also experience tiredness, headache, vomiting, decreased appetite, painful joints and muscle cramps.

I understand VIVITROL has been shown to treat alcohol and opioid dependence only when used as part of a treatment program that includes counseling and support. I will continue to participate in the support treatment after my release.

I understand that dizziness may occur with VIVITROL treatment, and I should avoid driving or operating heavy machinery until I have determined how VIVITROL affects me.

I should notify my physician if I:

- become pregnant or intend to become pregnant during treatment with VIVITROL.
- experience respiratory symptoms such as dyspnea, coughing, or wheezing when taking VIVITROL.
- experience any allergic reactions when taking VIVITROL.
- experience other unusual or significant side effects while on VIVITROL therapy.

By signing below,

- ❖ **I certify that I have read, or have had read to me all of the information indicated above, and that I understand all of the side effects, as well as my obligations, in regards to taking Vivitrol.**
- ❖ **I voluntarily consent to take Vivitrol as part of my treatment for opiate dependence.**
- ❖ **I voluntarily agree to ongoing opiate abuse counseling and treatment as part of the Vivitrol treatment program.**

PATIENT SIGNATURE	DATE SIGNED
PROVIDER SIGNATURE	DATE SIGNED