

Is Vivitrol[®] Right for You?

Stop the cravings and significantly reduce the risk of relapse



Vivitrol[®] and Counseling

Working Together. For You.

As part of my commitment for a meaningful recovery, I offer a non-addictive, non-narcotic based approach to medication assisted with therapy with Vivitrol for opiate and alcohol dependent patients.

Dr. Simon specializes in Addiction Medicine and Psychiatry,
Child & Adolescent Psychiatry as well as General Psychiatry.

JEFFREY SIMON MD
PSYCHIATRIST

800 Kings Highway North, Suite 506
Cherry Hill, New Jersey 08003

Phone: 856-685-6510

Fax: 856-382-7695

www.jeffreysimonmd.com

Alkermes[®] and VIVITROL[®] are registered trademarks of Alkermes, Inc.

What is Vivitrol?

(naltrexone for extended-release injectable suspension)
Vivitrol is a non-addictive, non-narcotic medication.

It does not react adversely with alcohol. It reduces cravings, helps achieve abstinence and blunts the effects of alcohol euphoria. Vivitrol also blocks the effects of opiates and reduces the cravings for opiates.

Vivitrol appears to break the self destructive, vicious cycle in alcoholics whereby one drink leads to multiple. When comparing abstinence rates at 6 months as a measure of success, studies have shown that Vivitrol works about 3 times better than counseling alone.

Vivitrol is indicated for opioid dependence which is generally viewed as a more intractable disease than alcoholism. In a study which included counseling, (like what is provided by Dr. Simon), 90% of those on Vivitrol were abstinent for 19 weeks compared to 35% of those on placebo.

In addition to improving compliance, the drug has an anti-craving effect and what the FDA called an anti-relapse effect. Patients who "slipped" (which is defined as a brief relapse) were better able to get

How Is Vivitrol Taken?

Vivitrol is injected by a healthcare provider once a month. Vivitrol is injected into a muscle in your buttocks using a special needle that comes with the medication. Once Vivitrol is injected it lasts for a month. It cannot be removed from the body. If you missed your appointment for a Vivitrol Injection, schedule another appointment as soon as possible. Be sure to tell your doctor that you are receiving Vivitrol injections.



Who Should Take Vivitrol?

Vivitrol is for the patient with Opioid-Dependency and/or Alcohol-Dependency who have had multiple relapses, who have failed multiple inpatient and outpatient treatment modalities, as well as 12-step participation, cognitive behavioral therapy, counseling with an addiction specialist and needs additional maintenance assisted therapy early in their recovery process for the prevention of relapse, following detox.

Who Should Not Take Vivitrol?

Patients with acute inflammation of the liver or have liver failure. Patients who are receiving opiates for analgesic reasons, whom may have chronic pain disease states that require intermittent or chronic opiates. Patient's currently going through acute opiate withdrawal detox should not receive Vivitrol. Patient's who are abusing or have a physical dependence on opioid-containing medicines or opioid street drugs.

Patient's must not take opioid-containing medicines, opioid street drugs, or opiate-like medication used in the detoxification process for at least 7-10 days before starting vivitrol.

To see whether you have a physical dependency on an opioid-containing medicine or opioid street drug, you may receive a small injection of a medicine called naloxone or receive oral naltrexone for 3 days. If you get symptoms of opiate withdrawal after the naloxone test, which may include: nausea, vomiting, headache, fatigue, dizziness, muscle cramps and joint pain, Vivitrol treatment should be delayed. If you have opioid withdrawal symptoms you should not take Vivitrol, these symptoms include: anxiety, sleeplessness, yawning, fever, sweating, periodic runny nose, response, shakiness, hot or cold flashes, muscle aches, muscle twitches, restlessness, nausea,

vomiting, diarrhea, or stomach cramps. Patients who have had allergic type reactions to naltrexone, or any components of the diluents which is the water-like material used to dissolve Vivitrol into a suspension.

What are the Precautions and Warnings of Vivitrol?

You should tell your healthcare provider about all the medications you are taking including prescriptions and nonprescription medications, over-the-counter medications, vitamins, and herbal supplements. Especially, tell your healthcare provider if you are taking an opioid - containing medicine for pain, cough or diarrhea. Reactions at the site of injection have occurred with Vivitrol. Some patients have had reactions at the site of injection including tissue death. Some of the injection site reactions have required surgery. You will need to call your healthcare provider immediately if you have any of the following injection site reactions:

- | | |
|------------------------|---------------|
| Intense Pain | Blisters |
| The area feels hard | An open wound |
| Large area of swelling | A dark scab |
| Lumps | |

Naltrexone, the active ingredient of Vivitrol can cause severe liver damage including liver failure or hepatitis, if you take more than the recommend dose. Notify your Healthcare provider if you have any of the following symptoms of liver problems during treatment with Vivitrol.

- Stomach area pain lasting more than a few days,
- Dark urine, Yellowing of the whites of your eyes,
- Tiredness.

There is a risk of Opioid overdose. If you have used opiate-containing medicines or opiate street drugs in the past, you have become more sensitive to lower doses or opiates. You may not feel the usual effects if you use or abuse heroin or other illegal street opioids while on Vivitrol.

What Should I Avoid While Taking Vivitrol?

Vivitrol-Naltrexone may make you feel dizzy, do not drive a car, operate machinery, or do other dangerous activities until you know how vivitrol effects you.

What Are Possible Side Effects of Vivitrol?

Depressed mood, sometimes leading to suicide, suicidal thoughts and behavior. Please tell all family members that you are on Vivitrol.

You or your family member should call your health-care provider right away if you become depressed or have any of the following symptoms:

- Feeling sad or have crying spells.
- Feeling disinterested in seeing friends or doing things you used to enjoy.
- Sleeping a lot more or a lot less than normal.
- Feeling hopeless or helpless.
- Being more irritable, angry, or aggressive than usual.
- Feeling more or less hungry than usual or notice a big change in your body weight.
- Having trouble paying attention.
- Feeling tired or sleepy all the time.
- Having thoughts of suicide.

Additional Side Effects of Vivitrol?

- Nausea – usually improves within a few days after the first Vivitrol injection; also, nausea is less likely with future injections of Vivitrol.
- Tiredness / Dizziness / Headache
- Painful Joints
- Muscle cramps
- Cold symptoms
- Toothache

Safety and Side Effects of Vivitrol®

As with all medications, Vivitrol® (naltrexone for extended-release injectable suspension) has potential side effects that you should know about.

Serious side effects

You should also know that Vivitrol might cause serious side effects, including:

Risk of opioid overdose

Using opioid, even in amounts that you used before Vivitrol treatment, can lead to accidental overdose, serious injury, coma, or death. To avoid accidental overdose:

- Do not take large amounts of opioids or try to overcome the opioid-blocking effects of Vivitrol.
- Do not use opioids in amounts that you used before Vivitrol treatment. You may even be more sensitive to lower amounts of opioids:
 - After detoxification
 - When your next Vivitrol dose is due
 - If you miss a dose of Vivitrol
 - After you stop Vivitrol treatment

Get emergency medical help right away if you have trouble breathing; have slow, shallow breathing; become very drowsy with slowed breathing; feel faint, dizzy, confused; or have other unusual symptoms.

Severe reactions at the site of injection

Vivitrol may cause severe injection site reactions, including tissue death. Some injection site reactions have required surgery. Call your doctor right away if you notice any of the following at your injection site: intense pain, the area feels hard, swelling, lumps, blisters, open wound or a dark scab.

Tell your doctor about any injection site reaction that concerns you.

Do not take large amounts of opioids, including opioid containing medicines, such as prescription pain pills, Heroin, cough medications with codeine, or any synthetic like opiate to overcome the effects of Vivitrol. This can lead to overdose including serious injury, coma, or death. You may not feel the usual effects of opioid-containing medicines including medicines for pain, cough, and diarrhea while on Vivitrol.

It is important that you tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose. If you have trouble breathing, become very drowsy with slow breathing, have slow - shallow breathing, feel faint or very dizzy, confused or have unusual symptoms you need to get emergency medical help right away. Some people on Vivitrol treatment have had severe allergic pneumonia. You may need to go to the hospital for treatment with antibiotic and steroid medications.

Call your healthcare provider if you have shortness of breath, sneezing or coughing that does not go away. Serious allergic reactions can happen during or soon after an injection of Vivitrol. Tell your healthcare professional right away if you have any of these symptoms of a serious allergic reaction.

Skin Rash

Swelling of the face, eyes, mouth, tongue

Trouble breathing or wheezing / Feeling dizzy or faint

Chest Pain.

If you are currently pregnant or plan to become pregnant, it is not known if Vivitrol-naltrexone will harm your baby. It is not known if Vivitrol-naltrexone passes to your milk if you are breastfeeding.

