

MEDICATION GUIDE

VIVITROL® [vīv´-ī-trôl] (naltrexone for extended-release injectable suspension)

Read this Medication Guide before you start getting VIVITROL injections and each time you get an injection. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about VIVITROL?

VIVITROL can cause serious side effects, including:

1. Severe reactions at the site of injection
2. Liver damage or hepatitis
3. Risk of opioid overdose
4. Severe allergic pneumonia
5. Serious allergic reactions

1. Severe reactions at the site of the injection. Some people on VIVITROL treatment have had severe reactions at the site of the injection (injection site reactions), including tissue death (necrosis). Some of these injection site reactions have required surgery. Call your doctor right away if you have any of the following things happen at any of your injection sites:

- intense pain
- the area feels hard
- large area of swelling
- lumps
- blisters
- an open wound
- a dark scab

Tell your doctor about any reaction at an injection site that concerns you, gets worse over time, or does not get better by two weeks after the injection.

2. Liver damage or hepatitis. Naltrexone, the active ingredient in Vivitrol, can cause liver damage (including liver failure) or hepatitis, if you take more than the recommended dose.

Tell your doctor 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

Your doctor may need to stop treating you with VIVITROL if you get signs or symptoms of a serious liver problem.

3. Risk of Opioid Overdose. If you have used opioid-containing medicines or opioid street drugs in the past, you may be more sensitive to lower doses of opioids:

- after VIVITROL treatment stops
- when your next VIVITROL dose is due
- if you miss a dose of VIVITROL

Using opioids in amounts that you used before treatment with VIVITROL can lead to overdose and death.

- You may not feel the usual effects if you use or abuse heroin and other illegal (street) opioids while on VIVITROL. Do not take large amounts of opioids, including opioid-containing medicines, such as prescription pain pills, or heroin, to overcome 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.

You or someone close to you should get emergency medical help right away if you:

- **have trouble breathing**
- **become very drowsy with slowed breathing**
- **have slow, shallow breathing (little chest movement with breathing)**
- **feel faint, very dizzy, confused, or have unusual symptoms**

4. Severe allergic pneumonia. Some people on VIVITROL treatment have had severe allergic pneumonia. Call your doctor if you have any of these symptoms:

- shortness of breath or wheezing
- coughing that does not go away

You may need to go to the hospital for treatment with antibiotic and steroid medicines.

5. Serious allergic reactions. Serious allergic reactions can happen during or soon after an injection of VIVITROL. Tell your doctor or get medical help right away if you have any of these symptoms of a serious allergic reaction.

- skin rash
- swelling of your face, eyes, mouth, or tongue

- trouble breathing or wheezing
- chest pain
- feeling dizzy or faint

6. Carry written information with you at all times to alert medical personnel that you are taking VIVITROL, so that they can treat you properly in an emergency.

What is VIVITROL?

VIVITROL is a prescription injectable medicine used:

- to treat alcohol dependence
- to prevent relapse to opioid dependence, after opioid detoxification
- You should stop drinking before starting VIVITROL.
- If you take opioids or opioid-containing medicine, such as prescription pain medicines, you must stop these opioids or medicines before starting VIVITROL.
- To be effective, treatment with VIVITROL must be used with other alcoholism or drug recovery programs such as counseling.

VIVITROL may not work for everyone.

VIVITROL has not been studied in children under the age of 18 years.

Who should not take VIVITROL?

Do not take VIVITROL if you:

- are using or have a physical dependence on opioid-containing medicines or opioid street drugs.
- You must not take opioid-containing medicines or opioid street drugs for 7 to 10 days before you start taking VIVITROL. See “What is the most important information I should know about VIVITROL?”
- To see whether you have a physical dependence on opioid-containing medicines or opioid street drugs, your doctor may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. If you get symptoms of opioid withdrawal after the naloxone challenge test, do not start treatment with VIVITROL at that time. Your doctor may repeat the test after you have stopped using opioids to see whether it is safe to start VIVITROL.
- have opioid withdrawal symptoms.
 - Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly

and then stop. These symptoms may include anxiety, sleeplessness, yawning, fever, sweating, teary eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps. (See “What is the most important information I should know about VIVITROL?”) Tell your doctor if you have any of these symptoms before taking VIVITROL.

- are allergic to VIVITROL or any of the ingredients in the liquid used to mix VIVITROL (diluent). See the end of this Medication Guide for a complete list of ingredients in VIVITROL and the diluent.

What should I tell my doctor before starting VIVITROL?

Tell your doctor about all of your medical conditions, including if you:

- have liver problems
- use opioid-containing medicines. **If you are being treated for alcoholism but also use or are addicted to opioid-containing medicines or opioid street drugs, it is important that you tell your doctor before starting VIVITROL to avoid having withdrawal symptoms when you start treatment.**
- use or abuse street (illegal) drugs
- have hemophilia or other bleeding problems
- have kidney problems
- are pregnant or plan to become pregnant. It is not known if VIVITROL will harm your unborn baby.
- are breastfeeding. It is not known if VIVITROL passes into your milk, and if it can harm your baby. Naltrexone, the active ingredient in VIVITROL, is the same active ingredient in tablets taken by mouth that contain naltrexone. Naltrexone from tablets passes into breast milk. Talk to your doctor about whether you will breast feed or take VIVITROL. You should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Especially tell your doctor if you take any opioid-containing medicines for pain, cough or colds, or diarrhea. (See “What is the most important information I should know about VIVITROL?”)

How should I take VIVITROL?

- VIVITROL is injected by a healthcare provider, about 1 time each month.
- VIVITROL is given as an injection into a muscle in your buttocks using a special needle that comes with VIVITROL.

- Once VIVITROL is injected, it lasts for a month and it cannot be removed from the body.
- If you miss your appointment for VIVITROL injection, schedule another appointment as soon as possible. See “What’s the most important information I should know about VIVITROL?”
- Whenever you need medical treatment, be sure to tell the treating doctor or nurse that you are receiving VIVITROL injections.

What should I avoid while taking VIVITROL?

VIVITROL may make you feel dizzy. Do not drive a car, operate machinery, or do other dangerous activities until you know how VIVITROL affects you. (See “What are the possible side effects of VIVITROL?”)

What are the possible side effects of VIVITROL?

VIVITROL can cause serious side effects.

- See “What is the most important information I should know about VIVITROL?”
- Depressed mood. Sometimes this leads to suicide, suicidal thoughts, and suicidal behavior. Tell your family members that you are taking VIVITROL.

You or a family member should call your doctor right away if you become depressed or have any of the following symptoms of depression, especially if they are new, worse, or worry you:

- You feel sad or have crying spells.
- You are no longer interested in seeing your friends or doing things you used to enjoy.
- You are sleeping a lot *more* or a lot *less* than usual.
- You feel hopeless or helpless.
- You are more irritable, angry or aggressive than usual.
- You are more or less hungry than usual or notice a big change in your body weight.
- You have trouble paying attention.
- You feel tired or sleepy all the time.
- You have thoughts about hurting yourself or ending your life.

Common side effects of VIVITROL include:

- nausea. Nausea usually improves within a few days after the first VIVITROL injection. Nausea is less likely with future injections of VIVITROL.

- tiredness
- headache
- dizziness
- vomiting
- decreased appetite
- painful joints
- muscle cramps

Common side effects in people taking VIVITROL for opioid dependence also include:

- cold symptoms
- trouble sleeping
- toothache

Tell your doctor about any side effect that bothers you or that does not go away.

These are not all the side effects of VIVITROL. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about VIVITROL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. VIVITROL was prescribed for your medical condition.

This leaflet summarizes the most important information about VIVITROL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about VIVITROL that is written for health professionals.

For additional information about VIVITROL call 1-800-848-4876 or visit www.vivitrol.com.

What are the ingredients in VIVITROL?

Active ingredient: naltrexone

Inactive ingredients: polylactide-co-glycolide (PLG)

Diluent ingredients: carboxymethylcellulose sodium salt, polysorbate 20, sodium chloride, and water for injection

Manufactured and marketed by:

Alkermes, Inc.

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This Medication Guide has been approved by the U.S. Food and Drug Administration
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