

Once-Monthly VIVITROL® May Give You A Path Forward

VIVITROL is a prescription injectable medicine used to treat alcohol dependence. You should stop drinking before starting VIVITROL.

To be effective, treatment with VIVITROL must be used with other alcohol or drug recovery programs such as counseling. VIVITROL may not work for everyone. It is not known if VIVITROL is safe and effective in children.

If you are being treated for alcohol dependence but also use opioid-containing medicines or opioid street drugs, it is important that you tell your healthcare provider before starting VIVITROL to avoid having sudden opioid withdrawal symptoms when you start VIVITROL treatment.

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



Actor portrayal

IMPORTANT SAFETY INFORMATION

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

VIVITROL can cause serious side effects, including:

- 1. Risk of opioid overdose.** You can accidentally overdose in two ways.
 - VIVITROL blocks the effects of opioids, such as heroin or opioid pain medicines. **Do not** try to overcome this blocking effect by taking large amounts of opioids—this can lead to serious injury, coma, or death.
 - After you receive a dose of VIVITROL, its blocking effect slowly decreases and completely goes away over time. If you have used opioid street drugs or opioid-containing medicines in the past, using opioids in amounts that you used before treatment with VIVITROL can lead to overdose and death. You may also be more sensitive to the effects of **lower** amounts of opioids:
 - after you have gone through detoxification
 - when your next VIVITROL dose is due
 - if you miss a dose of VIVITROL
 - after you stop VIVITROL treatment

Tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

Talk to your healthcare provider about naloxone,

a medicine that is available to patients for the emergency treatment of an opioid overdose.

Call 911 or get emergency medical help right away in all cases of known or suspected opioid overdose, even if naloxone is administered.

2. Severe reactions at the site of injection. Some people on VIVITROL have had severe injection site reactions, including tissue death. Some of these reactions have required surgery. VIVITROL must be injected by a healthcare provider. Call your healthcare provider right away if you notice any of the following 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 healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better within two weeks.

3. Sudden opioid withdrawal. To avoid sudden opioid withdrawal, you must stop taking any type of opioid, including street drugs; prescription pain medicines; cough, cold, or diarrhea medicines that contain opioids; or opioid-dependence treatments, including buprenorphine or methadone, **for at least 7 to 14 days** before starting VIVITROL. If your doctor decides that you don't need to complete detox first, he or she may give you VIVITROL in a medical facility that can treat sudden opioid withdrawal. **Sudden opioid**

withdrawal can be severe and may require hospitalization.

4. Liver damage or hepatitis. Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis. Tell your healthcare provider if you have any of these symptoms during treatment with VIVITROL:

- stomach area pain lasting more than a few days
- dark urine
- yellowing of the whites of your eyes
- tiredness

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

What are other possible serious side effects of VIVITROL?

VIVITROL can cause serious side effects, including:

Depressed mood. Sometimes this leads to suicide, or suicidal thoughts, and suicidal behavior. Tell your family members and people closest to you that you are taking VIVITROL.

Pneumonia. Some people receiving VIVITROL treatment have had a type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital.

Serious allergic reactions. Serious allergic reactions can happen during or soon after an injection of VIVITROL. Tell your healthcare provider or get medical help right away if you have any of these symptoms:

- skin rash
- swelling of your face, eyes, mouth, or tongue
- trouble breathing or wheezing
- chest pain
- feeling dizzy or faint

Common side effects of VIVITROL may include:

- nausea
- sleepiness
- headache
- dizziness
- vomiting
- decreased appetite
- painful joints
- muscle cramps
- cold symptoms
- trouble sleeping
- toothache

These are not all the side effects of VIVITROL. Tell your healthcare provider if you have any side effect that bothers you or that does not go away. You are encouraged to report all side effects to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This is only a summary of the most important information about VIVITROL.

Need more information?

- Ask your healthcare provider or pharmacist.

Please see full Prescribing Information and Medication Guide. Review Medication Guide with your healthcare provider.

This Brief Summary is based on the VIVITROL Medication Guide (Rev. March 2021).

Ask your healthcare provider if VIVITROL may be right for you



Learn more about VIVITROL

- Once-monthly shot injected by a healthcare provider
- Used in combination with counseling
- FDA approved to treat alcohol dependence since 2006
- 99% of insured patients are covered for VIVITROL^{1*}

*Coverage varies by health plan. You may have out-of-pocket costs. There may be additional requirements from your plan to obtain coverage. For information about your insurance coverage go to <https://www.vivitrol.com/my-insurance-coverage>, call 1-800-VIVITROL, or contact your plan administrator.



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Actor portrayal

What is VIVITROL?

VIVITROL is a prescription injectable medicine used to:

- treat alcohol dependence. You should stop drinking before starting VIVITROL.
- prevent relapse to opioid dependence, **after** opioid detoxification.

You must stop taking opioids before you start receiving VIVITROL. To be effective, VIVITROL must be used with other alcohol or drug recovery programs such as counseling. VIVITROL may not work for everyone. It is not known if VIVITROL is safe and effective in children.

Who should not receive VIVITROL?

Do not receive VIVITROL if you:

- are using or have a physical dependence on opioid-containing medicines or opioid street drugs, such as heroin. To test for a physical dependence on opioid-containing medicines or street drugs, your healthcare provider 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 healthcare provider may repeat the test after you have stopped using opioids to see whether it is safe to start VIVITROL.

- are having opioid withdrawal symptoms. Opioid withdrawal symptoms may happen when you have been taking opioid containing medicines or opioid street drugs regularly and then stop. **Symptoms of opioid withdrawal 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.

- are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL (diluent). See the medication guide for the full list of ingredients.

What should I tell my healthcare provider before receiving VIVITROL?

Before you receive VIVITROL, tell your healthcare provider if you:

- have liver problems, use or abuse street (illegal) drugs, have hemophilia or other bleeding problems, have kidney problems, or have any other medical conditions.
- 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 healthcare provider about whether you will breastfeed or take VIVITROL. You should not do both.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Especially tell your healthcare provider if you take any opioid-containing medicines for pain, cough or colds, or diarrhea.

If you are being treated for alcohol dependence but also use or are addicted to opioid-containing

medicines or opioid street drugs, it is important that you tell your healthcare provider before starting VIVITROL to avoid having sudden opioid withdrawal symptoms when you start VIVITROL treatment.

Please see full [Prescribing Information](#) and [Medication Guide](#). Review [Medication Guide](#) with your healthcare provider.

1. Data on file. Alkermes, Inc. Waltham, MA. Formulary data are provided by Decision Resources Group (DRG) Fingertip Formulary[®] and are current as of July 2022.



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