

Once-Monthly VIVITROL® May Give You A Path Forward

VIVITROL is a prescription injectable medicine used to prevent relapse to opioid dependence, after opioid detoxification.

You must stop taking opioids before you start receiving 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.

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



Actor portrayal

VIVITROL (naltrexone for extended-release injectable suspension) 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.

IMPORTANT SAFETY INFORMATION

VIVITROL can cause serious side effects, including:

- **Risk of opioid overdose.**
 - 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.**
- **Severe reactions at the site of injection.** Some people on VIVITROL have had severe injection site reactions, including tissue death. VIVITROL must be injected by a healthcare provider. Call your healthcare provider right away if you notice any of the following at the injection site: intense pain, the area feels hard, large area of swelling, lumps, blisters, an open wound, a dark scab,

or any reaction that concerns you, gets worse over time or does not get better within two weeks.

- **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.**
- **Liver damage or hepatitis.** Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis. Tell your healthcare provider if, during treatment, you have stomach area pain lasting more than a few days, dark urine, yellowing of the whites of your eyes, or tiredness. Your healthcare provider may need to stop treatment.

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 which 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).

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

- have liver problems, use or abuse street drugs, have hemophilia or other bleeding problems, have kidney problems, or have any other medical conditions.

(Continued on next page)

Click for full Prescribing Information and Medication Guide. Review Medication Guide with your healthcare provider.

Ask your healthcare provider if VIVITROL® may be right for you

- Once-monthly shot injected by a healthcare provider
- Used in combination with counseling
- FDA approved to treat opioid dependence since 2010
- 99% of insured patients are covered for VIVITROL, with 91% paying \$5 or less out of pocket*



Learn more about VIVITROL

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*Formulary data are provided by Decisions Resources Group Fingertip Formulary® and are current as of March 2023. IQVIATM: OPC Provider for the period of October 2021 – September 2022 reflecting estimates of real-world activity for the period of October 2021 – September 2022. Data accessed as of October 2022. All rights reserved. Coverage varies by health plan. For information about your insurance coverage go to <https://www.vivitrol.com/my-insurance-coverage>, call 1-800-VIVITROL, or contact your plan administrator.

IMPORTANT SAFETY INFORMATION (CONT'D)

Before you receive VIVITROL, tell your healthcare provider if you: (cont'd)

- 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.

What should I avoid while receiving VIVITROL?

Do not drive a car, operate machinery, or do other dangerous activities until you know how VIVITROL affects you. VIVITROL may make you feel dizzy and sleepy.

VIVITROL can cause other serious side effects, including:

- **Depressed mood**, which can sometimes lead to suicide, or suicidal thoughts, and suicidal behavior. You, a family member, or the people

closest to you should call your healthcare provider right away if you have these thoughts or symptoms especially if they are new, worse, or worry you.

- **Pneumonia caused by an allergic reaction.** If this type of pneumonia happens to you, you may need to be treated in the hospital.
- **Serious allergic reactions** that 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.

Read the Medication Guide, which is available at vivitrol.com and by calling 1-800-848-4876, option #1.

Click for full Prescribing Information and Medication Guide. Review Medication Guide with your healthcare provider.



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