Vivitrol[®] (naltrexone for extended-release injectable suspension)

HEALTHCARE PROVIDER DISCUSSION GUIDE

for Patients

VIVITROL® (naltrexone for extended-release injectable suspension) is a non-addictive, once-monthly treatment proven to prevent relapse in opioid-dependent patients when used with counseling following opioid detoxification.¹ See page 4 for the most important information you should know about VIVITROL.

> A conversation with a healthcare provider may help you decide what is right for you. In addition, he or she may be able to answer questions about your recovery journey. This discussion guide was created to help you get the conversation started.

RELAPSE¹

Looking for a VIVITROL provider?

Visit VIVITROL.com/find-a-treatment-provider

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.

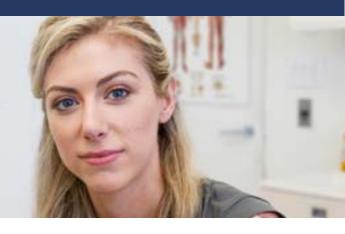
Reference:

1. VIVITROL [prescribing information]. Waltham, MA: Alkermes, Inc; rev March 2021.

PLEASE SEE <u>BRIEF SUMMARY OF IMPORTANT FACTS</u> ABOUT VIVITROL ON PAGES 4 AND 5. PLEASE ALSO SEE <u>PRESCRIBING INFORMATION</u> AND <u>MEDICATION GUIDE</u>. REVIEW MEDICATION GUIDE WITH YOUR HEALTHCARE PROVIDER.







VIVITROL IS A ONCE-

MONTHLY TREATMENT

PROVEN TO PREVENT

TALKING WITH A HEALTHCARE PROVIDER

Asking questions is key to a good conversation with your healthcare provider. You may want to ask about available treatment options, including VIVITROL. You can also develop a plan with your healthcare provider and then explore the reasons why the chosen plan is right for you.



Here are some topics and questions to consider during your appointment:

ABOUT VIVITROL

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

Have you prescribed VIVITROL in the past?

Can opioid-containing medicines be taken while on VIVITROL?

How would I receive VIVITROL, and where would I get it?

Am I eligible for the VIVITROL Co-pay Savings Program?

TREATMENT GOALS

What types of short- and long-term treatment goals belong in a treatment plan?

How do my personal goals fit into my treatment plan?

Can relapse to opioid dependence be prevented? Can VIVITROL help?

Are there options to help me decrease my opioid cravings? Is VIVITROL an option?

IMPORTANT INFORMATION ABOUT VIVITROL

VIVITROL can cause serious side effects, including:

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 if you miss a dose of VIVITROL
- when your next VIVITROL dose is due 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.

PLEASE SEE <u>BRIEF SUMMARY OF IMPORTANT FACTS</u> ABOUT VIVITROL ON PAGES 4 AND 5. PLEASE ALSO SEE <u>PRESCRIBING INFORMATION</u> AND <u>MEDICATION GUIDE</u>. REVIEW MEDICATION GUIDE WITH YOUR HEALTHCARE PROVIDER.

COUNSELING AND SETTINGS OF CARE	
Should therapy and/or counseling be part of my recovery treatment plan?	What treatment settings should I consider? (hospital or other medical facilities)
What are my counseling options?	Are there programs that would allow me to live at home and continue to work?
Will opioid detox be a part of my treatment plan?	Does opioid detox require hospitalization?
my treatment plan?	Can you tell me more about Medically Supervised

Is opioid detox required before taking VIVITROL?

Withdrawal from opioids?

Additional Questions and Notes:

Have more questions for your healthcare provider? Write them below or on a separate piece of paper.

As you move forward with this Healthcare Provider Discussion Guide, remember that there are no right or wrong questions. Just be honest and open with your healthcare provider.

IMPORTANT INFORMATION ABOUT VIVITROL

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.

PLEASE SEE <u>BRIEF SUMMARY OF IMPORTANT FACTS</u> ABOUT VIVITROL ON PAGES 4 AND 5. PLEASE ALSO SEE <u>PRESCRIBING INFORMATION</u> AND <u>MEDICATION GUIDE</u>. REVIEW MEDICATION GUIDE WITH YOUR HEALTHCARE PROVIDER. (NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION)

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

- an open wound
- the area feels hard blisters a dark scab

• lumps

large area of swelling

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 yellowing of the whites of your eyes
 - dark urine
 tiredness

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

What is VIVITROL?

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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.

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PLEASE CONTINUE TO READ <u>BRIEF SUMMARY OF IMPORTANT FACTS</u> ABOUT VIVITROL ON THE NEXT PAGE. PLEASE ALSO SEE <u>PRESCRIBING INFORMATION</u> AND <u>MEDICATION GUIDE</u>. REVIEW MEDICATION GUIDE WITH YOUR HEALTHCARE PROVIDER.



(NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION) (cont'd)

Do not receive VIVITROL if you:

- 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.

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

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

Common side effects of VIVITROL may include:

• nausea

dizziness

- painful joints
- trouble sleeping

- sleepinessheadache
- vomiting
 decreased appet
- muscle cramps
 cold symptoms
- toothache

- decreased appetite
- cold symptoms
- **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 <u>www.fda.gov/medwatch</u>, 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.

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

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

PLEASE ALSO SEE <u>PRESCRIBING INFORMATION</u> AND <u>MEDICATION GUIDE</u>. REVIEW MEDICATION GUIDE WITH YOUR HEALTHCARE PROVIDER.



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