

For Alcohol Dependence

# HELP REINFORCE YOUR RECOVERY

Treat alcohol dependence with a **once-monthly treatment** used with counseling.

VIVITROL® is a prescription injectable medicine used to:

- Treat alcohol dependence. You should stop drinking before starting VIVITROL.
- To be effective, VIVITROL must be used with other alcohol or drug recovery programs, such as counseling.
- It is not known if VIVITROL is safe and effective in children.



**See important information about possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL on pages 5-6. This information does not take the place of talking with your healthcare provider.**

**Vivitrol**<sup>®</sup>  
(naltrexone for extended-release  
injectable suspension)

# ARE YOU OR YOUR LOVED ONE READY TO **MOVE FORWARD?**

Alcohol addiction is a chronic brain disease defined by an uncontrollable urge to seek and use alcohol. Because addiction changes the way the brain works, most patients need ongoing care in the form of counseling and medication.<sup>1</sup>

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking the button in the top right-hand corner. This information does not take the place of talking with your healthcare provider.

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## FIGHT ALCOHOL DEPENDENCE WITH A **ONCE-MONTHLY TREATMENT AND COUNSELING**<sup>2</sup>

### **VIVITROL® (naltrexone for extended-release injectable suspension) is a prescription injectable medicine used to:**

- Treat alcohol dependence. You should stop drinking before starting VIVITROL.
- To be effective, VIVITROL must be used with other alcohol or drug recovery programs, such as counseling.
- It is not known if VIVITROL is safe and effective in children.

### **You should not receive VIVITROL if you:**

- Are using or have physical dependence on opioid-containing medicines or opioid street drugs.
- 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.
- Are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL.

### **VIVITROL:**

- ✓ Opioid blocker
- ✓ HCP-administered
- ✓ Once-monthly injectable
- ✓ Used with counseling
- ✓ Non-addictive
- ✓ Not a narcotic
- ✓ Requires opioid detox

**Before starting VIVITROL, you must be opioid-free for a minimum of 7 to 14 days to avoid sudden opioid withdrawal.**

**Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.**

**See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking the button in the top right-hand corner. This information does not take the place of talking with your healthcare provider.**

### **Is there a risk of opioid overdose with VIVITROL?**

**Yes. One serious side effect of VIVITROL is the risk of opioid overdose.** Using opioids, even in amounts that you used before VIVITROL treatment, can lead to accidental overdose, serious injury, coma, or death.

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

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.



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## VIVITROL AND COUNSELING: PROVEN TO TREAT ALCOHOL DEPENDENCE

### ► PRIMARY ENDPOINT<sup>3</sup>

Patients treated with VIVITROL and counseling experienced fewer heavy drinking days\* per month compared to placebo.



In the treatment population of a 6-month, double-blind, placebo-controlled, randomized clinical study, compared to patients being treated with a placebo and counseling (n=209), patients treated with VIVITROL and counseling (n=205) experienced:

- 25% fewer heavy drinking days compared to placebo\*

### ► SUBSET POPULATION

This study included a pre-specified subset of VIVITROL and placebo patients (n=53 or 8% of total study population) who abstained from alcohol completely during the week prior to their first dose. In this population<sup>2</sup>:

- 17 patients on VIVITROL had 0.2 heavy drinking days compared to 2.5 heavy drinking days for 19 patients on placebo.<sup>4</sup>
- This amounts to 92% fewer heavy drinking days for VIVITROL patients.<sup>4</sup>

The same results were not seen in the subset (n=571, or 92% of the total study population) of patients who were actively drinking at the time of starting treatment.<sup>2</sup>

\*Heavy drinking was defined as a self-report of 5 or more standard drinks consumed on a given day for male patients and 4 or more drinks for female patients.

## Is there a risk of severe reactions at the injection site with VIVITROL?

**Yes. One serious side effect of VIVITROL is severe reactions at the site of the injection, including tissue death.** Some injection site reactions have required surgery. Call your healthcare provider right away if you notice any of the following at your injection site:

- Intense pain
- The area feels hard
- Swelling
- Lumps
- Blister
- An open wound
- A dark scab

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



Vials shown are not actual size

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking the button in the top right-hand corner. This information does not take the place of talking with your healthcare provider.

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## BRIEF SUMMARY OF IMPORTANT FACTS ABOUT VIVITROL<sup>®</sup> (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.

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

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?

#### 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.

→ Brief Summary of Important Facts about VIVITROL continues on the following page.

## 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
- 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](http://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.

**Read the Medication Guide, which is available at [VIVITROL.com](http://VIVITROL.com) and by calling 1-800-848-4876, option #1.**

This Brief Summary is based on the VIVITROL Medication Guide (Rev. July 2019).

**References:** **1.** American Society of Addiction Medicine. Definition of addiction. <https://www.asam.org/quality-practice/definition-of-addiction>. Accessed March 17, 2020. **2.** VIVITROL [prescribing information]. Waltham, MA: Alkermes, Inc; rev September 2019. **3.** Garbutt JC, Kranzler HR, O'Malley SS, et al. Efficacy and tolerability of long-acting injectable naltrexone for alcohol dependence: a randomized controlled trial. *JAMA*. 2005;293(13):1617-1625. **4.** Data on file. Alkermes, Inc. Waltham, MA.

The recovery journey is a fight, but there are medications that can help. Ask your healthcare provider if VIVITROL and counseling may be a treatment option for your alcohol dependence.

Learn more at  
**VIVITROL.com**

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