# PATIENT COUNSELING TOOL
## VIVITROL® (naltrexone for extended-release injectable suspension)

Review this guide with your patient each time they have a scheduled VIVITROL injection.

### 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.

### Risk of sudden opioid withdrawal during initiation and reinitiation of VIVITROL

Using any type of opioid including street drugs, prescription pain medicines, cough, cold, or diarrhea medicines that contain opioids, or opioid dependence treatments buprenorphine or methadone in the 7 to 14 days before starting VIVITROL may cause severe and potentially dangerous sudden opioid withdrawal.

### Risk of opioid overdose

**Patients may be more sensitive to the effects of lower amounts of opioids:**

- After stopping opioids (detoxification)
- When the next VIVITROL dose is due
- If a dose of VIVITROL is missed
- After VIVITROL treatment stops

Patients should tell their family and people close to them about the increased sensitivity to opioids and the risk of overdose even when using lower doses of opioids or amounts that they used before treatment. Using large amounts of opioids, such as prescription pain pills or heroin, to overcome effects of VIVITROL can lead to serious injury, coma, and death.

### Patient access to naloxone for the emergency treatment of opioid overdose

Because of the vulnerability to opioid overdose described above, discuss with the patient and caregiver the importance of having access to naloxone, and inform them of options for obtaining it, as permitted by individual state naloxone dispensing and prescribing requirements or guidelines (e.g., by prescription, directly from a pharmacist, or as part of a community-based program).

Educate patients and caregivers on how to recognize the signs and symptoms of an opioid overdose.

Explain to patients and caregivers that naloxone's effects are temporary, and that they must call 911 or get emergency medical help right away in all cases of known or suspected opioid overdose, even if naloxone is administered.

### Risk of severe reactions at the injection site

Remind patients of these **possible** symptoms at the **injection site**:

- Intense pain
- The area feels hard
- Large areas of swelling
- Lumps
- Blisters
- Open wound
- Dark scab

Some of these injection site reactions have required surgery.

Tell your patients to contact a healthcare provider if they have any reactions at the injection site.

### Risk of liver injury, including liver damage or hepatitis

**Remind patients of the possible symptoms of liver damage or hepatitis.**

- Stomach area pain lasting more than a few days
- Dark urine
- Yellowing of the whites of eyes
- Tiredness

**Patients may not feel the therapeutic effects of opioid-containing medicines for pain, cough or cold, or diarrhea while taking VIVITROL.**

**Patients should carry written information with them at all times to alert healthcare providers that they are taking VIVITROL, so they can be treated properly in an emergency.**
**A Patient Wallet Card or Medical Alert Bracelet can be ordered from: 1-800-848-4876, Option #3.**

**Please see additional IMPORTANT SAFETY INFORMATION on the next page.**
**Click for full Prescribing Information and Medication Guide.**

## 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.
- 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.**

Alkermes®



**vivitrol.com**

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