# PATIENT SAFETY CARD FOR EMERGENCY PAIN MANAGEMENT

If you ever need emergency medical treatment, your Pain Management Card lets other doctors and nurses know that you are taking VIVITROL® (naltrexone for extended-release injectable suspension). This card includes information that will help them provide you with the best possible care.

If you are being treated with VIVITROL, it is important that you print this page, cut out the card below, fold in half and tape shut. Keep card with you at all times and updated with your last injection date.



### **INDICATIONS**

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.

Please see <u>Important Safety Information</u> below and full <u>Prescribing</u> <u>Information</u> and <u>Medication Guide</u> at <u>vivitrol.com</u>.



# **IMPORTANT SAFETY INFORMATION (CONT'D)**

- Risk of opioid overdose. (cont'd)
  - After you receive a dose of VIVITROL® (naltrexone for extended-release injectable suspension), 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.

Please see <u>Important Safety Information</u> below and full <u>Prescribing Information</u> and <u>Medication Guide</u> at <u>vivitrol.com</u>.

## **IMPORTANT SAFETY INFORMATION (CONT'D)**

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\* (naltrexone for extended-release injectable suspension) 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 <a href="www.fda.gov/medwatch">www.fda.gov/medwatch</a>, 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.



Use this code or visit <u>VIVITROL.com/content/pdfs/emergency-pain-management-card.pdf</u> to download additional cards.

Please see <u>Important Safety Information</u> above and full <u>Prescribing Information</u> and <u>Medication Guide</u> at <u>vivitrol.com</u>.

