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MEDICATION GUIDE

VIVITROL® [vĭv´-ĭ-trôl]
(naltrexone for extended-release injectable suspension)

Read this Medication Guide before you start getting VIVITROL injections and each time you get an injection. There may be new information. This information does not take the place of talking to your doctor about your medical condition or your treatment.

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

1. Some people on VIVITROL treatment have had severe reactions at the site of the injection (injection site reactions), including tissue death (necrosis). Some of these injection site reactions have required surgery. Call your doctor right away if you have any of the following things happen at any of your injection sites:

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

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

2. The active ingredient in VIVITROL (naltrexone) has been associated with liver damage (including liver failure) or hepatitis when given in amounts greater than the recommended dose. VIVITROL does not appear to cause liver damage or hepatitis at the recommended dose.

   Tell your doctor if you have any of the following symptoms of liver problems:

   - stomach area pain lasting more than a few days
   - dark urine
   - yellowing of the whites of your eyes
   - tiredness

3. VIVITROL blocks the effects of opioid-containing medicines and opioid street drugs.

   - You may not feel the usual effects of opioid-containing medicines including medicines for pain, cough and diarrhea while on VIVITROL.

   - You may not feel the usual effects if you use or abuse heroin and other illegal (street) opioids while on VIVITROL.

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- Do not take large amounts of opioids, including opioid-containing medicines, such as prescription pain pills, or heroin, to overcome effects of VIVITROL. This can lead to overdose including serious injury, coma, or death.

- If you have used opioid-containing medicines or opioid street drugs in the past, you may be more sensitive to lower doses of opioids after VIVITROL treatment stops. This can lead to overdose.

4. Some people on VIVITROL treatment have had severe allergic pneumonia.

    - Call your doctor immediately if you have shortness of breath, coughing, or wheezing. You may need to go to the hospital for treatment with antibiotic and steroid medicines.

5. Carry written information with you at all times to alert medical personnel that you are taking VIVITROL, so that they can treat you properly in an emergency.

What is VIVITROL?

- VIVITROL is a prescription injectable medicine used to treat alcohol dependence in adults 18 years and older.
- You should stop drinking before starting VIVITROL.
- To be effective, treatment with VIVITROL must be used along with other alcoholism recovery programs such as counseling.

VIVITROL may not work for everyone.
VIVITROL has not been studied in children under the age of 18 years.

Who should not take VIVITROL?

Do not take VIVITROL if you:

- are using and/or have a physical dependence on opioid-containing medicines or opioid street drugs.
    - You must not take opioid-containing medicines or opioid street drugs for 7-10 days before you start taking VIVITROL. (See “What is the most important information I should know about VIVITROL?”)
    - To see whether you have a physical dependence on opioid-containing medicines or opioid street drugs, your doctor may give you a small injection of a medicine called naloxone. This is called a naloxone challenge test. If you develop symptoms of opioid withdrawal after the naloxone challenge test, you should not start treatment with VIVITROL at that time. Your doctor may repeat the test after you have stopped using opioids to see whether it is safe to start VIVITROL.

- have opioid withdrawal symptoms.
    - Opioid withdrawal symptoms may occur when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop. These symptoms may include anxiety, sleeplessness, yawning, fever, sweating, teary

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eyes, runny nose, goose bumps, shakiness, hot or cold flushes, muscle aches, muscle twitches, restlessness, nausea and vomiting, diarrhea, or stomach cramps. (See "What is the most important information I should know about VIVITROL?")

- are allergic to VIVITROL or any of the ingredients in the liquid used to mix VIVITROL (diluent). See the end of this leaflet for a complete list of ingredients in VIVITROL and the diluent.

What should I tell my doctor before starting VIVITROL?

Tell your doctor about all of your medical conditions, including if you:

- have liver problems
- use opioid-containing medicines
- use or abuse street (illegal) drugs
- have hemophilia or other bleeding problems
- have kidney problems
- 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 doctor about whether you will breast feed or take VIVITROL; you should not do both.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins and herbal supplements. Especially tell your doctor if you take any opioid-containing medicines for pain, cough, or diarrhea. (See "What is the most important information I should know about VIVITROL?")

How should I take VIVITROL?

- VIVITROL is given as an injection into a muscle in your buttocks using a special needle that comes with VIVITROL.
- VIVITROL is injected by a healthcare provider, about once a month.
- Once VIVITROL is injected, it lasts for a month and it cannot be removed from the body.
- If you miss your appointment for VIVITROL injection, schedule another appointment as soon as possible. Whenever you need medical treatment, be sure to tell the treating doctor or nurse that you are receiving VIVITROL injections.

What should I avoid while taking VIVITROL?

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VIVITROL may make you feel dizzy. Do not drive a car, operate machinery, or do other dangerous activities until you know how VIVITROL affects you. (See "What are the possible side effects of VIVITROL?")

What are the possible side effects of VIVITROL?

VIVITROL can cause serious side effects. (See "What is the most important information I should know about VIVITROL?")

Other serious side effects include: depressed mood, sometimes leading to suicide, suicidal thoughts, and suicidal behavior. Tell your family members that you are taking VIVITROL.

You or a family member should call your doctor right away if you become depressed or have any of the following symptoms of depression, especially if they are new, worse, or worry you:

- You feel sad or have crying spells.
- You are no longer interested in seeing your friends or doing things you used to enjoy.
- You are sleeping a lot *more* or a lot *less* than usual.
- You feel hopeless or helpless.
- You are more irritable, angry or aggressive than usual.
- You are more or less hungry than usual or notice a big change in your body weight.
- You have trouble paying attention.
- You feel tired or sleepy all the time.
- You have thoughts about hurting yourself or ending your life.

Common side effects of VIVITROL include:

- nausea. Nausea usually improves within a few days after the first VIVITROL injection. Nausea is less likely with future injections of VIVITROL.
- tiredness
- headache
- dizziness
- vomiting
- decreased appetite
- painful joints
- muscle cramps

Tell your doctor about any side effect that bothers you or that does not go away.

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These are not all the side effects of VIVITROL. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about VIVITROL

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. VIVITROL was prescribed for your medical condition.

This leaflet summarizes the most important information about VIVITROL. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about VIVITROL that is written for health professionals. For additional information about VIVITROL call 1-800-848-4876 or visit www.vivitrol.com.

What are the ingredients in VIVITROL?

Active ingredient: naltrexone
Inactive ingredients: polylactide-co-glycolide (PLG)
Diluent ingredients: carboxymethylcellulose sodium salt, polysorbate 20, sodium chloride, and water for injection

This Medication Guide has been approved by the U.S. Food and Drug Administration

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