

MEDICATION GUIDE

VIVITROL® (viv-i-trol) (naltrexone for extended-release injectable suspension)

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

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** take large amounts of opioids, including opioid-containing medicines, such as heroin or prescription pain pills, to try to overcome the opioid-blocking effects of VIVITROL. 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

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.

You or someone close to you should 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, very dizzy, confused, or have unusual symptoms

2. Severe reactions at the site of the injection (injection site reactions).

Some people on VIVITROL have had severe injection site reactions, including tissue death (necrosis). Some of these injection site reactions have required surgery. Call your healthcare provider right away if you notice any of the following 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 healthcare provider 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.

3. Sudden opioid withdrawal.

Anyone who receives a VIVITROL injection must not use any type of opioid (must be opioid-free) including street drugs, prescription pain medicines, cough, cold, or diarrhea medicines that contain opioids, or opioid dependence treatments, buprenorphine or methadone, **for at least 7 to 14 days** before starting VIVITROL. Using opioids in the 7 to 14 days before you start receiving VIVITROL may cause you to suddenly have symptoms of opioid withdrawal when you get the VIVITROL injection. **Sudden opioid withdrawal can be severe, and you may need to go to the hospital.**

You must be opioid-free before receiving VIVITROL unless your healthcare provider decides that you don't need to go through detox first. Instead, your doctor may decide to give your VIVITROL injection in a medical facility that can treat you for sudden opioid withdrawal.

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 the following symptoms of liver problems during treatment with VIVITROL:

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

This means that if you take opioids or opioid-containing medicines, you must stop taking them before you start receiving VIVITROL. **See "What is the most important information I should know about VIVITROL?"**

To be effective, treatment with 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. **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 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. **See “What is the most important information I should know about VIVITROL?”** Tell your healthcare provider if you have any of these symptoms before taking VIVITROL.

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

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
- 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. **See “What is the most important information I should know about VIVITROL?”**

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.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How will I receive VIVITROL?

- VIVITROL is injected by a healthcare provider, about 1 time each month.
- VIVITROL is given as an injection into a muscle in your buttocks using a special needle that comes with VIVITROL.
- After VIVITROL is injected, it lasts for a month and it cannot be removed from the body.
- If you miss your appointment for your VIVITROL injection, schedule another appointment as soon as possible. **See “What is the most important information I should know about VIVITROL?”**
- Whenever you need medical treatment, be sure to tell the treating healthcare provider that you are receiving VIVITROL injections and mention when you got your last dose. This is important because VIVITROL can also block the effects of opioid-containing medicines that might be prescribed for you for pain, cough or colds, or diarrhea.
- Carry written information with you at all times to alert healthcare providers that you are taking VIVITROL, so that they can treat you properly in an emergency. Ask your healthcare provider how you can get a wallet card to carry with you.

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. **See “What are the possible side effects of VIVITROL?”**

What are the possible side effects of VIVITROL?

VIVITROL can cause serious side effects, including:

- **See “What is the most important information I should know about VIVITROL?”**

- **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.

You, a family member, or the people closest to you should call your healthcare provider 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.
- **Pneumonia.** Some people receiving VIVITROL treatment have had a certain type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital. Tell your healthcare provider right away if you have any of these symptoms during treatment with VIVITROL:
 - shortness of breath or wheezing
 - coughing that does not go away
 - **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 of a serious allergic reaction.
 - 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. Nausea may happen after your first VIVITROL injection and usually improves within a few days. Nausea is less likely with future injections of VIVITROL.
- sleepiness
- headache
- dizziness
- vomiting
- decreased appetite
- painful joints

- muscle cramps
- cold symptoms
- trouble sleeping
- toothache

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the side effects of VIVITROL. For more information, ask your healthcare provider 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. This Medication Guide summarizes the most important information about VIVITROL. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about VIVITROL that is written for health professionals.

For more information about VIVITROL call 1-800-848-4876, Option #1 or go to 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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