



VIVITROL® [vīv'ĭ-trōl]

Rx only

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**Manufactured and marketed by:
Alkermes, Inc.
88 Sidney St.
Cambridge, MA 02139**

What is VIVITROL?

VIVITROL is an injectable medicine for the treatment of alcohol dependence in adults 18 years and older.

To benefit from VIVITROL, you need to stop drinking before starting the medicine.

To be effective, treatment with VIVITROL must be used along with other alcoholism recovery measures such as counseling.

VIVITROL may not work for everyone.

VIVITROL has not been studied in children under the age of 18 years.

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

1. VIVITROL may be associated with liver damage or hepatitis.
 - Call your doctor if you develop stomach area pain lasting more than a few days, light-colored bowel movements, dark urine, or yellowing of your eyes.
2. VIVITROL blocks the effects of opioid-containing medicines.
 - You may not feel the same effects of opioid-containing medicines including medicines for pain, cough and diarrhea.
 - You may not feel the same effects if you use or abuse heroin and other illegal (street) opioids.
 - Do not take large amounts of opioid medicines to overcome the VIVITROL block. This can lead to serious injury, coma, or death.
3. VIVITROL has been associated with severe allergic pneumonia.
 - Call your doctor if you develop shortness of breath, coughing or wheezing.

Who should not take VIVITROL?

Do not take VIVITROL if you:

- Are taking or have a physical dependence on opioid-containing medicines. (See “What is the most important information I should know about VIVITROL?”)
- Use or have a physical dependence on opioid street drugs. (See “What is the most important information I should know about VIVITROL?”)
- Are allergic to VIVITROL. The active ingredient is naltrexone. See the end of this leaflet for a complete list of ingredients in VIVITROL.

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 can harm your unborn baby.
- Are breastfeeding. It is not known if VIVITROL passes into your milk, and if it can harm your baby.

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?”)

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

How do I take VIVITROL?

VIVITROL is given as a “shot” (injection) in your buttocks. It is injected by your healthcare provider about once a month. Because VIVITROL is an injection, once it is given you cannot remove it 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?

VIVITROL may make you feel dizzy. Do not drive a car, work with machines, 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 may cause side effects including:

- A reaction at the injection site. The reaction could be pain, tenderness, swelling, redness, and/or itching. Tell your doctor if the reaction gets worse over time.
- Nausea.

The other common side effects of VIVITROL are:

- Headache
- Fatigue
- Dizziness
- Vomiting
- Decreased appetite
- Painful joints
- Muscle cramps

Tell your doctor about 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 doctor or pharmacist.

General information about VIVITROL

Medicines are sometimes prescribed for conditions other than those listed in patient information leaflets. 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 and treatment support for alcohol dependence 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: carboxymethylcellulose sodium salt, polysorbate 20, sodium chloride, and water



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