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Vivitrol

# Vivitrol 🕁

Generic name: naltrexone

Dosage form: extended-release intramuscular injection (powder for suspension)

Drug class: Drugs used in alcohol dependence

Medically reviewed by Philip Thornton, DipPharm. Last updated on Mar 25, 2025.

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## What is Vivitrol?

Vivitrol is a long-acting injectable form of naltrexone, which is a medication used to treat two substance use disorder - opioid use disorder and alcohol use disorder (alcoholism). Vivitrol is used as part of a treatment program. It helps prevent people with alcohol or opioid dependence from feeling like they need to use these substances.

Vivitrol is an opioid antagonist, which works by blocking mu opioid receptors. It also suppresses the amount of alcohol you feel like drinking by changing how your hypothalamus, pituitary gland and adrenal gland work together. Vivitrol blocks the intoxication and euphoria or 'high' that alcohol and opioids cause. It also blocks the pain relief that opioids provide.

Vivitrol is an extended-release suspension that is injected into your gluteal muscle. Once injected, it slowly releases naltrexone (the active ingredient) for about a month.

Vivitrol was first approved by the US Food and Drug Administration in 2006.

## What is Vivitrol used for?

Vivitrol is a prescription injectable medicine used to:

- treat alcohol dependence. You should stop drinking before starting this medication.
- prevent relapse to opioid dependence, after opioid detoxification.
   This means that if you take opioids or opioid-containing medicines (sometimes called narcotics), you must stop taking them before you start receiving this medication. See Important information below.

To be effective, treatment with Vivitrol must be used with other alcohol or drug recovery programs such as counseling. This treatment may not work for everyone.

It is not known if Vivitrol is safe and effective in children.

## Important information

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 this medication. 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:
  - o after you have gone through detoxification
  - when your next Vivitrol dose is due
  - o if you miss a dose of this medication
  - o after you stop treatment with this medication

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 call 911 or 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)
- o feel faint, very dizzy, confused, or have unusual symptoms

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.

- 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. This medication must be injected by a healthcare provider. 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 treatment with this medication. 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 your 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 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 this medication if you get signs or symptoms of a serious liver problem.

## 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 'Important information' above.

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 this medication.

- 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

- o fever
- sweating
- o teary eyes
- o runny nose
- o goose bumps
- o shakiness
- hot or cold flushes
- muscle aches
- o muscle twitches
- o restlessness
- o nausea and vomiting
- o diarrhea
- stomach cramps

See 'Important information' above. 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 below for a complete list of ingredients.
- Vivitrol pregnancy and breastfeeding warnings (more detail)

## What should I tell my doctor 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

## How should I receive Vivitrol?

- Vivitrol is injected by a healthcare provider, about 1 time each month.
- Vivitrol must be injected by a healthcare provider. Do not attempt to inject yourself with this medication. Serious reactions, some that may require hospitalization, might happen.
- · Vivitrol is given as an injection into a muscle in your buttocks using a special needle that comes with it.
- After Vivitrol is injected, it lasts for a month and it cannot be removed from the body.

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 this medication 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 this medication, 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.

Vivitrol patient tips (more detail)

## What happens if I miss a dose?

If you miss your appointment for your Vivitrol injection, schedule another appointment as soon as possible. See 'Important information' above.

## 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. It may make you feel dizzy and sleepy. See 'What are the possible side effects of Vivitrol?' below.

## **Dosing information**

The recommended dose of Vivitrol is 380 mg delivered intramuscularly (IM) as a gluteal injection, every 4 weeks or once a month, alternating buttocks for each subsequent injection.

See Full Prescribing Information for further information about dosing.

Detailed Vivitrol dosage information

## What are the side effects of Vivitrol?

Serious side effects of Vivitrol include:

- See 'Important information' above
- 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.

- o 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
  - o 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
  - o swelling of your face, eyes, mouth, or tongue
  - trouble breathing or wheezing
  - chest pain
  - o feeling dizzy or faint

#### Common side effects of Vivitrol 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.

i <u>Vivitrol side effects</u> (more detail)

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## **Interactions**

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 'Important information' above.

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.

<u>Vivitrol drug interactions</u> (more detail)

## Does Vivitrol interact with my other drugs?

Enter medications to view a detailed interaction report using our Drug Interaction Checker.

(	Vivitrol	
•	+	
E	Enter a drug name	Add

## Pregnancy and breastfeeding

Tell your healthcare provider if you are pregnant or plan to become pregnant. It is not known if Vivitrol will harm your unborn baby.

Tell your healthcare provider if you are breastfeeding or plan to breastfeed. It is not known if naltrexone, the active ingredient in Vivitrol, passes into your milk when administered by IM injection, and if it can harm your baby. 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.

## **Storage**

- Store the entire dose pack in the refrigerator (2°C to 8°C, 36°F to 46°F).
- Vivitrol can be stored outside of a refrigerator at temperatures not exceeding 25 °C (77 °F) for no more than 7 days prior to administration. Do not expose the product to temperatures above 25 °C (77 °F).
- Vivitrol should not be frozen.

Keep out of Reach of Children.

## What are the ingredients in Vivitrol?

Active ingredient: naltrexone

Inactive ingredients: polylactide-co-glycolide (PLG)

Diluent ingredients: carboxymethylcellulose sodium, polysorbate 20, sodium chloride, sodium hydroxide and hydrochloric acid as pH adjusters, in water for injection.

Vivitrol is manufactured and marketed by Alkermes, Inc. 852 Winter Street Waltham, MA 02451-1420

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#### References

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Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

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#### **Availability**

Rx Prescription only

**Pregnancy & Lactation** 

ঝ্য Risk data available

**CSA Schedule\*** 

N/A Not a controlled drug

**Approval History** 

Drug history at FDA

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