HELP
REINFORCE
YOUR RECOVERY

Treat opioid or alcohol dependence with a non-addictive, once-monthly treatment used with counseling.1,2

See important information about possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL on pages 19–20. This information does not take the place of talking with your healthcare provider.
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 detox.
- You must stop taking opioids or other opioid-containing medications before starting VIVITROL.
- To be effective, VIVITROL must be used with other alcohol or drug recovery programs, such as counseling.
- It is not known if VIVITROL is safe and effective in children.

You should not take VIVITROL if you:

- Are using or have physical dependence on opioid-containing medicines or opioid street drugs.
- Have opioid withdrawal symptoms. Opioid withdrawal symptoms may happen when you have been taking opioid-containing medicines or opioid street drugs regularly and then stop.
- Are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix VIVITROL.

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.

ARE YOU READY TO MOVE FORWARD ON YOUR RECOVERY JOURNEY?

We know that opioid and alcohol dependence can be devastating, both psychologically and physically. But you are not alone. Counseling can help you work through the psychological aspects of dependence, and medications can help address the physical changes in the brain.

When you are ready to take the next step, VIVITROL and counseling may help you on your path to recovery.
Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects. See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button below. This information does not take the place of talking with your healthcare provider.
UNDERSTANDING ADDICTION

WHAT IS VIVITROL?

HOW VIVITROL AND COUNSELING MAY HELP

GETTING STARTED ON VIVITROL

BRIEF SUMMARY OF IMPORTANT FACTS ABOUT VIVITROL
**Understanding Addiction**

Addiction is a chronic, relapsing brain disease that changes how the brain works and affects behavior. Addiction is defined by an uncontrollable urge to seek and use drugs or alcohol, despite the problems they cause. People with addiction cannot simply stop using drugs or alcohol for a few days and be cured of their addiction. Most patients need ongoing care. Treatment programs include counseling and social support to treat the psychological aspects of addiction. They may also include medication to help treat the physical effects of addiction.

**Cortical Targets**
- **Cortical Targets**
  - Decision-making
  - Thinking
  - Reasoning
  - Planning

**Limbic Region Targets**
- **Limbic Region Targets**
  - Basic drives or urges
  - Rewards
  - Pleasure

**The Psychological Benefits of Counseling**
- The psychological effects of addiction are very powerful. That’s why addressing these effects is so important—especially when someone is starting recovery. Counseling teaches people effective recovery skills to help prevent relapse.
  - Self-acceptance and personal growth
  - Developing positive life skills and habits
  - Coping with relapse triggers, stressors, and urges
  - Reducing the urge to use opioids

Counseling and a strong support network are essential to helping people recover and stay in recovery.

**The Physical Effects Can Be Treated with Medication**
- Medications for treating opioid addiction work by interacting with some of the same receptors in the brain that are triggered by drugs. Medication can help in treating the physical effects of addiction, and should be used alongside counseling.

**There Are Three Types of Medication Used with Counseling**
- Full agonist
- Partial agonist
- Antagonist (blocking medication)
HOW DOES ADDICTION AFFECT THE BRAIN?

To understand how addiction happens, it is important to understand how the brain normally works.

Normal brain
The human brain is stimulated by everything you do. When you do something you enjoy (such as eating delicious food), your brain releases chemicals called endorphins. Endorphins attach to opioid receptors in the brain causing them to release a chemical called dopamine. Dopamine gives you a good feeling to reward you for doing something, which makes you want to repeat these behaviors.4,6

The brain and alcohol use
Drinking alcohol can cause an increased release of endorphins, which in turn can trigger the release of an increased amount of dopamine. For some people, this may result in an alcohol-induced euphoria, or “high.” When the good feeling ends, the brain makes some people want that feeling again, so they seek it out again and again. This urge can be very powerful. This is often a characteristic of alcoholism.4,6

Developing tolerance
As the brain builds up a tolerance, you need more alcohol or opioids to feel the same way as that first time. Over time, the body often becomes physically dependent on alcohol or opioids to feel normal and avoid the symptoms of withdrawal.4

The brain and opioid use
Illicit opioids (such as heroin) and opioid pain medications attach to some of the same receptors as endorphins. However, opioids cause the receptors in your brain to release a greater amount of dopamine than normal enjoyable activities do, causing an intense pleasurable feeling, or “high.” When the high ends, the brain craves the feeling again.4,6
TREATING DEPENDENCE WITH MEDICATION

There are three types of medication used with counseling to treat opioid dependence: agonists, partial agonists, and antagonists.5

**Agonist medication**
Agonists attach to and activate opioid receptors like illicit opioids or prescription drugs. When taken as directed, agonists have a stabilizing effect, preventing withdrawal symptoms. Patients don’t have to detox to start on an agonist medication, but they will experience withdrawal when they stop taking the medication because agonists prolong dependence on opioids.7,9

Partial agonist medication
Partial agonists attach to opioid receptors, but do not stimulate them to the same degree as full agonists. When taken as directed, partial agonists have a stabilizing effect, preventing withdrawal symptoms. Patients don’t have to detox to start on a partial agonist medication, but they will experience withdrawal symptoms when they stop because partial agonists prolong dependence on opioids.9,10

Antagonist or blocking medication
Antagonists also attach to opioid receptors, but do not cause the release of dopamine. They are non-addictive and do not lead to physical dependence. Antagonists create a barrier that blocks opioid molecules from attaching to opioid receptors. Patients must detox before starting an antagonist.7,8

Medication options for opioid dependence7,11,12

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<thead>
<tr>
<th></th>
<th>AGONIST THERAPY</th>
<th>PARTIAL AGONIST THERAPY</th>
<th>ANTAGONIST THERAPY</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Setting</strong></td>
<td>Provided at certified opioid treatment program settings</td>
<td>The film or tablet can be initially provided in a physician’s office then as a take-home medication. The six-month implant and monthly injection require healthcare provider administration.</td>
<td>Daily oral medication can be provided as take-home medication. Monthly injection requires healthcare provider administration.</td>
</tr>
<tr>
<td><strong>Requires detox</strong></td>
<td>NO</td>
<td>NO</td>
<td>YES</td>
</tr>
<tr>
<td><strong>Requires counseling</strong></td>
<td>YES</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

This chart is not intended to make any product comparisons, and no comparisons of safety or efficacy of any products are to be made.

→ Discuss all the benefits and risks of agonist, partial agonist, and antagonist medications with a healthcare provider.

These images are for illustrative purposes only.
WHAT IS VIVITROL?

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
WHAT IS VIVITROL?

VIVITROL® (naltrexone for extended-release injectable suspension) is a non-addictive, once-monthly treatment for opioid and alcohol dependence. It is an antagonist medication that blocks opioid receptors in the brain for one month at a time, helping patients to prevent relapse to opioid dependence, following detox, and fight alcohol dependence while they focus on counseling.1,2

VIVITROL1,2:
- Opioid receptor blocker
- Non-addictive
- HCP-administered
- Once-monthly injectable
- Used with counseling
- Not a narcotic
- Requires opioid detox
- Requires opioid detox

How VIVITROL works1:

VIVITROL® is an antagonist that blocks opioid molecules from attaching to opioid receptors.

Is there a risk of opioid overdose with VIVITROL?

Yes. One serious side effect of VIVITROL is the risk of opioid overdose. Using opioids, even in amounts that you used before VIVITROL treatment, can lead to accidental overdose, serious injury, coma, or death.

- Do not take large amounts of opioids or try to overcome the opioid-blocking effects of VIVITROL.
- 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

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, dizzy, confused or have other unusual symptoms.

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.

I’m choosing to move forward, and if there’s something out there that’s going to help me, then I’m going to use it.
— Kurt, father and counselor on recovery journey

Watch Kurt’s story on VIVITROL.com/Kurt to learn how he used VIVITROL along with a drug counseling program to help reinforce his recovery process.

This image is for illustrative purposes only.

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects. 

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
HOW VIVITROL AND COUNSELING MAY HELP WITH OPIOID AND ALCOHOL DEPENDENCE

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
TREATING OPIOID DEPENDENCE WITH VIVITROL®
(NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION) AND COUNSELING¹,²

When used as part of a treatment plan that includes counseling, VIVITROL can help prevent relapse to opioid dependence after detox. During a 6-month, double-blind, placebo-controlled, randomized clinical study, opioid-dependent patients being treated with a placebo and counseling (n=124) were compared to opioid-dependent patients being treated with VIVITROL and counseling (n=126):

- **Primary Endpoint**
  - 90% had 90% opioid-free weeks (compared to 35% with a placebo)* P=0.0002

- **Secondary Endpoint**
  - 55% had a 55% decrease in self-reported opioid craving from baseline. (Placebo increased 3% from baseline)³ P<0.0001 (adjusted)
  - 17x were 17x less likely to relapse to physical dependence compared to placebo (1 patient on VIVITROL compared to 17 patients on placebo, P<0.0001)

- **Secondary Endpoint**
  - 96 Days
  - Placebo
  - >168 Days
  - Vivitrol

*Confirmed abstinence was defined as a negative urine drug test for opioids and no self-reported opioid use for all weekly visits.

³Craving was measured by self-reported “need for opioids” using a visual analog scale.

Is there a risk of severe reactions at the injection site with VIVITROL?

Yes. Some people on VIVITROL have had severe injection site reactions, including tissue death. Some of these reactions have required surgery. VIVITROL 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
- Swelling
- Lumps
- Blisters
- An open wound
- A dark scab

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

Is there a risk of sudden opioid withdrawal when starting VIVITROL?

Yes. One serious side effect of VIVITROL is sudden opioid withdrawal. You must stop taking any opioids or opioid-containing medications, including buprenorphine or methadone, for at least 7 to 14 days before starting VIVITROL. If your healthcare provider 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.

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.
When added to counseling, VIVITROL may help you reduce heavy-drinking days.

**Primary Endpoint**

<table>
<thead>
<tr>
<th>25%</th>
<th>92%</th>
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<td>P=0.02</td>
<td>P=0.005</td>
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In the overall treatment population of a 6-month, double-blind, placebo-controlled, randomized clinical study, patients treated with VIVITROL and counseling (n=205) demonstrated a **25% greater reduction** in days of heavy-drinking\(^*\) than those treated with a placebo and counseling (n=209).

A pre-specified subset (n=53, or 8.3% of total study population) who abstained from alcohol completely during the week prior to their first dose of VIVITROL and counseling compared to placebo and counseling experienced:

- **92% fewer** heavy-drinking days\(^*\)
  - 0.2 heavy-drinking days on VIVITROL compared to 2.5 heavy-drinking days on placebo

The same results were not seen in the subset (n=571, or 92% of the total study population) of patients who were actively drinking at the time of starting treatment.

\(^*\)Heavy-drinking was defined as a self-report of 5 or more standard drinks consumed on a given day for male patients and 4 or more drinks for female patients.

- **Can VIVITROL cause liver damage or hepatitis?** Yes. One serious side effect of VIVITROL is 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 VIVITROL treatment:
  - 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.

- **If my healthcare provider is considering VIVITROL treatment for my alcohol dependence, do I need to tell my healthcare provider that I take opioids?** Yes. 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 medications you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
GETTING STARTED ON VIVITROL

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
VIVITROL®
(NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION)
IS A **ONCE-MONTHLY MEDICATION**

If you and your healthcare provider have decided VIVITROL is right for you, it is important for you to **prepare for your monthly injection appointments**.

› **How will 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 VIVITROL. 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 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.
  - 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 can I do for pain management while on VIVITROL?**

In the event that you need medical treatment, be sure to tell your healthcare provider that you are receiving VIVITROL treatment and the date of your last injection. This is important because VIVITROL can also block the effects of opioid-containing medicines that might be necessary to block pain in an emergency.

While on VIVITROL, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required, it should be administered by specially trained healthcare providers and the patient should be monitored closely.

**Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you.** Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
Once you are prescribed VIVITROL, it is important to try to avoid delays in getting your VIVITROL medication. By following a few steps and working closely with your healthcare provider and the specialty or other pharmacy, you have the resources you need to help you stay on track in your recovery journey.

To receive your VIVITROL injection:

1. **With your healthcare provider:**
   - Complete the specialty pharmacy form
   - Provide your insurance card (if applicable)
   - Discuss the VIVITROL® Co-pay Savings Program
   Your healthcare provider will then send the form to the specialty pharmacy.

2. **The specialty or other pharmacy:**
   - Confirms insurance coverage with your health plan
   - Applies any co-pay savings you are eligible for
   Expect a call from your pharmacy to coordinate the delivery of your first prescription.
   - You will be contacted by the pharmacy or Vivitrol2gether™ to verify:
     - Payment
     - Shipping
     - Delivery
   - Upon approval, the prescription will be filled and shipped to your healthcare provider’s office.

3. **Visit your healthcare provider to receive your VIVITROL injection on your appointment date**

4. **Schedule your next appointment**

   **Repeat steps 2-3**

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**HELPFUL HINTS:**

- **Has your phone number changed?** If so, be sure to update your healthcare provider and pharmacy with your new number.
- **Consider designating a family member or loved one as a secondary contact for VIVITROL.** In case you are not available to authorize a shipment, update your pharmacy with your secondary contact’s phone number.

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**INFORMATION YOU’LL NEED TO START VIVITROL:**

Keep this information handy as you consider getting your first injection of VIVITROL.

1. **Remember to answer or return calls from your pharmacy.**
   - Helpful tips for the pharmacy call:
     - A. Most health plans cover VIVITROL. If you are eligible for the VIVITROL® Co-pay Savings Program, be prepared to give your program ID #.
       - ID #: ____________________
     - B. You may be asked for your credit card information to cover any insurance co-pay that is due.

2. **Keep in mind when and where you will receive your first VIVITROL injection.** Consider adding a reminder on your mobile calendar.
   - A. Date/Time: ____________________
   - B. Address: ____________________

3. **If you need to change healthcare providers,** reach out to the Vivitrol2gether™ team for help with transitioning to a new provider. Your team can notify the pharmacy of the new provider’s address. Consider adding this information to your contacts.
   - A. New Provider Name/Phone #: ____________________
   - B. Address: ____________________

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**GETTING STARTED ON VIVITROL**

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

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Check Your Health Plan’s Coverage
If you are considering treatment with VIVITROL® (naltrexone for extended-release injectable suspension), you can check your insurance coverage with your health plan ahead of time. Call Vivitrol2getherSM at 1-800-VIVITROL (1-800-848-4876) Monday–Friday, 9am–8pm (EST) to learn more or visit VIVITROL.com.

VIVITROL Provider Locator
The VIVITROL Provider Locator is an online resource that connects you with healthcare providers who can prescribe and/or administer VIVITROL in your area.

VIVITROL® Co-pay Savings Program
If you need help paying for VIVITROL, the VIVITROL® Co-pay Savings Program may assist eligible* patients with out-of-pocket expenses for their VIVITROL prescriptions. The co-pay savings program may cover up to $500/month of co-pay or deductible expenses. Terms and Conditions apply.* Visit VIVITROLCopay.com to learn more.

Terms and Conditions
*Eligibility for Alkermes-Sponsored Co-pay Savings. This offer is only available to patients 18 years or older, with a prescription consistent with the Prescribing Information and the patient is not enrolled in, or covered by, any local, state, federal or other government program that pays for any portion of medication costs, including but not limited to Medicare, including Medicare Part D or Medicare Advantage plans; Medicaid, including Medicaid Managed Care and Alternative Benefit Plans under the Affordable Care Act; Medigap; VA; DOD; TRICARE; or a residential correctional program.

Additional Terms of Use: This offer is not conditioned on any past, present, or future purchase, including refills. Alkermes reserves the right to rescind, revoke, or amend this offer, program eligibility, and requirements at any time without notice. This offer is limited to one per patient, may not be used with any other offer, is not transferable and may not be sold, purchased or traded, or offered for sale, purchase or trade. Void where prohibited by law. Program Administrator or its designee will have the right upon reasonable prior written notice, during normal business hours, and subject to applicable law, to audit compliance with this program.

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

See important information on possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.
QUESTIONS TO ASK YOUR HEALTHCARE PROVIDER

If you are considering VIVITROL® (naltrexone for extended-release injectable suspension), these questions might help start the conversation with your healthcare provider:

1. Is VIVITROL right for me?
2. What is the most important information I should know?
3. What should I know about possible side effects?
4. Do you need to know all medications I am taking, including supplements?
5. How do I schedule my injections?
6. Where do I go to get my injections?

Ask your healthcare provider for a VIVITROL wallet card, bracelet, or dog tag that you can wear to alert healthcare providers that you are on VIVITROL in the event that you need pain management treatment, or call 1-800-VIVITROL (1-800-848-4876).

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

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SAVING ON YOUR VIVITROL® TREATMENT

The program covers up to $500/month of co-pay or deductible expenses for eligible patients. Terms and Conditions apply.*

To learn more about the VIVITROL® Co-pay Savings Program, visit VIVITROLCopay.com

For more information about the VIVITROL® Co-pay Savings Program, visit VIVITROLCopay.com

I am still continuing to discover who I am. I realize that I’ve always been a strong person. That is something I didn’t realize before.

— Carrie, mother and counselor on recovery journey

*Patient stories reflect personal experiences. Individual experiences may vary.
BRIEF SUMMARY OF IMPORTANT FACTS ABOUT VIVITROL®
(NALTREXONE FOR EXTENDED-RELEASE INJECTABLE SUSPENSION)

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 try to overcome this blocking effect by taking large amounts of opioids—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

Tell your family and the people closest to you of this increased sensitivity to opioids and the risk of overdose.

2. Severe reactions at the site of injection. Some people on VIVITROL have had severe injection site reactions, including tissue death. Some of these reactions have required surgery. VIVITROL 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

Tell your healthcare provider about any reaction at an injection site that concerns you, gets worse over time, or does not get better within two weeks.

3. 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.

Discuss all benefits and risks of VIVITROL with your healthcare provider and whether VIVITROL may be right for you. Call your healthcare provider for medical advice about any side effects.

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 these symptoms 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.

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.

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, 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. 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, tearful 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). See the medication guide for the full list of ingredients.
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, 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 crosses 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.

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.

What are other possible serious side effects of VIVITROL?

VIVITROL can cause serious side effects, including:

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.

Pneumonia. Some people receiving VIVITROL treatment have had a type of pneumonia that is caused by an allergic reaction. If this happens to you, you may need to be treated in the hospital.

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:

- 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
- 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 www.fda.gov/medwatch, or call 1-800-FDA-1088.

This is only a summary of the most important information about VIVITROL.

Need more information?
- Ask your healthcare provider or pharmacist.

Read the Medication Guide, which is available at vivitrol.com and by calling 1-800-848-4876, option #1.

This Brief Summary is based on the VIVITROL Medication Guide (Rev. July 2019).

Recovery is a fight, but there are medications that can help. Ask your healthcare provider if VIVITROL and counseling may be an effective way to help treat your opioid or alcohol dependence.

Learn more at VIVITROL.com

See important information about possible side effects with VIVITROL treatment throughout this brochure. Read the Brief Summary of Important Facts about VIVITROL by clicking on the gray button to the right. This information does not take the place of talking with your healthcare provider.