# ARE YOU READY TO MOVE FORWARD?

Helping you take the next steps in recovery from opioid dependence or alcoholism





# When you decide to get started... we're here to help you keep moving forward

If you're looking for information about how medication can support your treatment plan, this brochure may help.

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## VIVITROL is a once-monthly medication

When used with counseling, it has been shown to be effective for:

- → Treating alcohol dependence (alcoholism). You should stop drinking before starting VIVITROL
- → Preventing relapse to opioid dependence after opioid detox. You must stop taking opioids or other opioid-containing medications before starting VIVITROL

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.



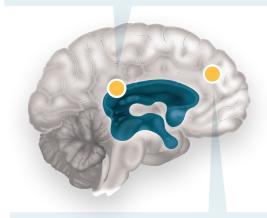
Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

## Why should VIVITROL be used with counseling?

VIVITROL can be part of a comprehensive treatment plan that targets two regions of the brain affected by addiction.

#### Medication targets the limbic region<sup>2-5</sup>

- Basic drives or urges
- Rewards
- Pleasure



### Counseling targets the cortex<sup>2,3</sup>

- Decision-making
   Learning
- Thinking
- Willpower

- Reasoning

Please read the <u>Prescribing Information</u> and <u>Medication</u> Guide. This information does not take the place of talking with your doctor.



# What to consider about treatment with VIVITROL

### VIVITROL is:1

- → A long-acting injection, which means it only has to be administered once a month
- → Clinically proven
- → An effective complement to 12-step and other counseling programs

#### VIVITROL is not:1

- A narcotic
- Addictive
- Pleasure-producing

### Taking VIVITROL:1

- → Won't prolong your dependence on opioids or alcohol
- Doesn't replace or act as a substitute for opioids or alcohol
- Will not result in withdrawal when stopping VIVITROL treatment

### Who should not take VIVITROL?

You should not take VIVITROL if you:

- → Are still using or still have any symptoms of physical withdrawal due to dependence on opioid street drugs or opioid-containing medicines
- → Have opioid withdrawal symptoms
- → Are allergic to naltrexone or any of the ingredients in VIVITROL or the liquid used to mix it

See the <u>Medication Guide</u> for complete information about opioid withdrawal and the ingredients in VIVITROL and the liquid used to mix it.

Before starting VIVITROL, you must be opioid-free for a minimum of 7–10 days to avoid sudden opioid withdrawal **that may be severe enough to require hospitalization**. More information to follow.

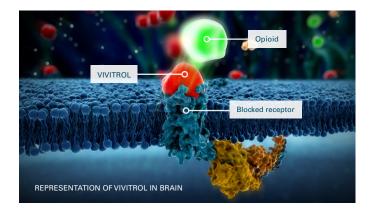
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## How VIVITROL may work in the brain

The active ingredient in VIVITROL, naltrexone, is an **opioid antagonist** or **blocker** 



VIVITROL blocks the effects of opioids in the brain's reward system. When opioids are in your body, they send signals to the brain's reward system, creating a feeling of pleasure that can often lead to addiction. VIVITROL helps block these signals.

How VIVITROL works in treating alcoholism is not completely understood. VIVITROL is believed to block the pleasurable feelings produced by drinking.

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# VIVITROL can cause serious side effects

### 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. To avoid accidental overdose:

- → Do not take large amounts of opioids or try to overcome the opioid-blocking effects of VIVITROL
- → Do not use opioids in amounts that you used before VIVITROL treatment. You may even be more sensitive to **lower** amounts of opioids:
  - o After detox
  - o When your next VIVITROL dose is due
  - o If you miss a dose of VIVITROL
  - o 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; feel faint, very dizzy, confused, or have 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.

Please read the <u>Prescribing Information</u> and <u>Medication</u> <u>Guide</u>. This information does not take the place of talking with your doctor.





## How can VIVITROL® help?

When used as part of a treatment plan including counseling, VIVITROL could help with your recovery journey. Read the study results to see how it has helped others with opioid dependence or alcoholism.

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## Opioid dependence



## VIVITROL® and opioid dependence

When added to counseling, VIVITROL may help with recovery

You never expected to become addicted, and recovery can be hard. But there is a non-addictive medication that may help.

A study showed that opioid-dependent patients who participated in counseling and took VIVITROL after detox had better results than patients who participated in counseling without VIVITROL.

## Opioid-dependent patients participating in counseling plus VIVITROL:

- → Had significantly more days of complete abstinence\*
- → Stayed in treatment longer
- → Reported less craving<sup>†</sup>
- → Were less likely to relapse to physical dependence

# VIVITROL can cause serious side effects

Sudden opioid withdrawal

To avoid 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 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.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

Please read the <u>Prescribing Information</u> and <u>Medication</u> <u>Guide</u>. This information does not take the place of talking with your doctor.

<sup>\*</sup>Complete abstinence was defined as a negative urine drug test for opioids and no self-reported opioid use for all weekly visits.

<sup>†</sup>Craving was measured by self-reported "need for opioids" using the visual analog scale.



## VIVITROL® and alcohol dependence

When added to counseling, VIVITROL may help with recovery

If you're ready to commit to recovery, there is an abstinence-based medication that may help.

A study of alcohol-dependent patients who participated in counseling with VIVITROL compared to those patients who participated in counseling without VIVITROL had the following results:

## Alcohol-dependent patients participating in counseling plus VIVITROL had:

→ Significantly fewer heavy drinking days<sup>‡</sup>

\*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.

# A small group of alcohol-dependent patients who completely stopped drinking one week prior to their first dose of VIVITROL (with counseling) had:

- → Significantly fewer drinking days
- → More success maintaining complete abstinence

The same results were not seen in patients who were drinking when they started VIVITROL.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

# VIVITROL can cause serious side effects

### Liver damage or hepatitis

Naltrexone, the active ingredient in VIVITROL, can cause liver damage or hepatitis. Tell your doctor if you have any of the following symptoms of liver problems during VIVITROL treatment:

- Stomach area pain lasting more than a few days
- → Yellowing of the whites of your eyes
- → Dark urine
- → Tiredness

Your healthcare provider may need to stop treating you with VIVITROL if you get signs or symptoms of a serious liver problem.

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.

Please read the <u>Prescribing Information</u> and <u>Medication</u> <u>Guide</u>. This information does not take the place of talking with your doctor.



## VIVITROL is long-acting

### It is only administered once a month

VIVITROL is given as an injection in the buttocks by a healthcare provider about 1 time each month. After the VIVITROL injection is given, the medication stays in your body for 1 month and cannot be removed.

If you and your doctor decide VIVITROL is right for you, it's important to keep each of your injection appointments as recommended by your doctor. If you miss an appointment, try to schedule another one with your doctor as soon as possible.



## Keep your injection appointments

Whenever you need medical treatment, be sure to tell your doctor 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 necessary to block pain in an emergency.

Visit <u>vivitrol.com/painmanagementcard</u> to print a pain management card. You should fill out and carry this card with you at all times.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

# VIVITROL can cause serious side effects

### Severe reactions at the injection site

VIVITROL may cause severe injection site reactions, including tissue death. Some injection site reactions have required surgery. Call your doctor right away if you notice any of the following at your injection site:

- → Intense pain
- → The area feels hard
- → Swelling
- → Lumps
- → Blisters
- → An open wound
- → A dark scab

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

Please read the <u>Prescribing Information</u> and <u>Medication</u> <u>Guide</u>. This information does not take the place of talking with your doctor.



# 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 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 doctor about whether you will breastfeed or take VIVITROL. You should not do both.

### **Before starting VIVITROL treatment:**

Tell your doctor about all the medications you take, including prescription and nonprescription medications, vitamins, and herbal supplements.

Especially tell your doctor if you take any opioidcontaining medicines for pain, cough or colds, or diarrhea.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

## Can I get help paying for VIVITROL?

You may be eligible for savings

The VIVITROL® Co-Pay Savings Program<sup>™</sup> could help with treatment costs. If you are eligible,\* **you may qualify for \$0 co-pay**.



## If you are interested in this program, you can get more info by:

- → Asking your doctor
- → Visiting <u>vivitrol.com/savings</u>

\*Eligibility for Alkermes-Sponsored Co-pay Assistance: This offer is valid up to a maximum of \$500 per month, and only for prescriptions for FDA-approved indications. You must be at least 18 years old. If you are receiving benefits from Medicaid, Medicare, or TRICARE® — or another federal or state healthcare program, including any state medical or pharmaceutical assistance program — you are not eligible for this offer. Void where prohibited by law, taxed or restricted. Alkermes, Inc. reserves the right to rescind, revoke or amend these offers without notice.

Please read the <u>Prescribing Information</u> and <u>Medication</u> <u>Guide</u>. This information does not take the place of talking with your doctor.



## Filling your VIVITROL® prescription

If you and your doctor decide VIVITROL is right for you, this information will help you understand how your prescription will be filled and what you need to do in the process.

Because VIVITROL is given as an injection and requires special handling, prescriptions are managed by a specialty pharmacy.



## 4 steps to getting your prescription

- 1 Your doctor prescribes VIVITROL.
- 2 A specialty pharmacy fills your prescription.
  - → Your specialty pharmacy may call you each month to confirm your prescription. It's important that you return this call so VIVITROL can be delivered to your doctor.
  - → If you don't hear from your specialty pharmacy at least 5 days before each scheduled injection, call your doctor to make sure your prescription will be ready.
- 3 Your VIVITROL prescription is delivered directly to your doctor.
- 4 You get your injection and schedule your next appointment.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

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# Other possible serious and common side effects



# VIVITROL® can cause other serious side effects, such as:

- → Depressed mood Sometimes this leads to suicide or suicidal thoughts and behavior.

  Tell those closest to you that you are taking VIVITROL. You or those closest to you should call your doctor right away if you become depressed or have any new or worsening depression symptoms.
- → Allergic pneumonia Tell your doctor if you have shortness of breath, wheezing, or a cough that doesn't go away.
- → Serious allergic reactions Get medical help immediately if you have a skin rash; swelling of your face, eyes, mouth, or tongue; trouble breathing or wheezing; chest pain; or are feeling dizzy or faint.

# Common side effects of VIVITROL may include:

- → Nausea
- → Tiredness
- → Headache
- → Dizziness
- → Vomiting
- → Decreased appetite
- → Painful joints
- → Muscle cramps
- → Cold symptoms
- → Trouble sleeping
- → Toothache

These are not all of the side effects of VIVITROL. For more information, ask your healthcare provider. Tell your doctor right away if you have any side effect that does not go away. See the <u>Medication Guide</u> for more information.

Call your doctor for medical advice about any side effects. You are encouraged to report negative side effects to the FDA. Visit <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> or call 1-800-FDA-1088.

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#### References

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