



Meeting the Need

Doing more to help address the crisis of opioid and alcohol dependence

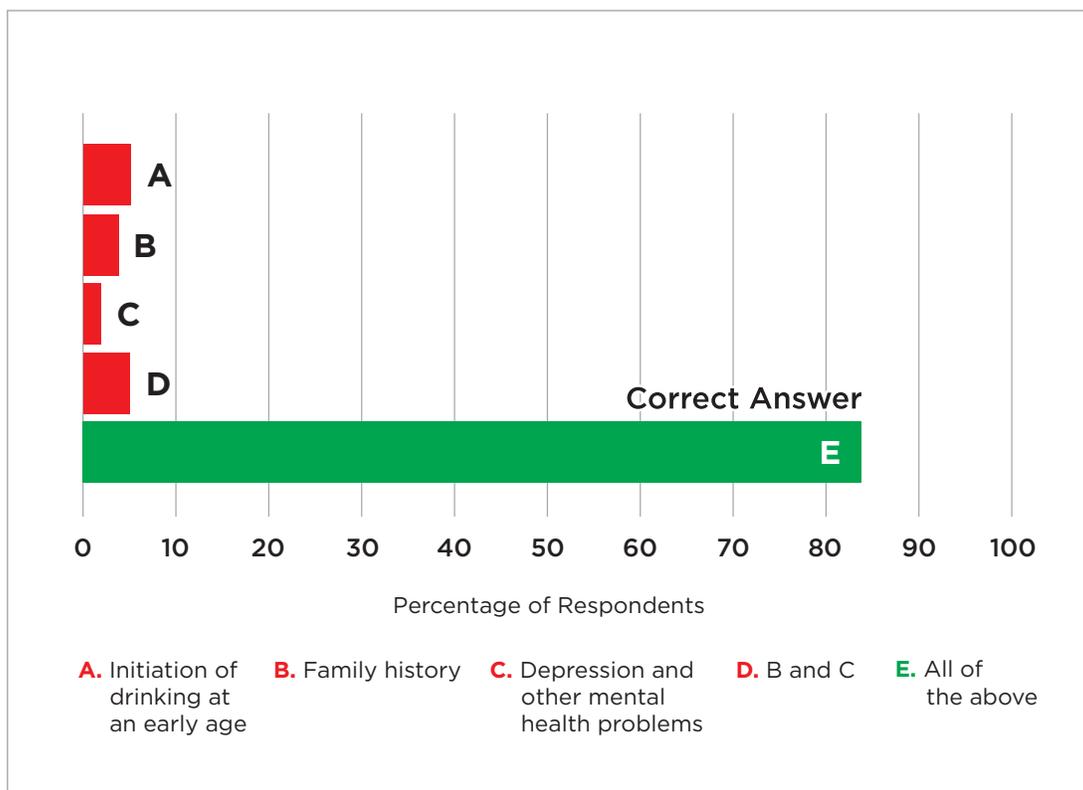
Quiz Results

Understanding the Burden of Alcohol Dependence

Note: A total of 413 completed quizzes were received as of the date of this report (January 22, 2018).

Question 1 of 5: Which of the following is considered a risk factor for alcohol dependence?

Finding: The majority of respondents, but not all, appear to have a good understanding of the multiple risk factors for alcohol dependence.



Explanation

Alcohol dependence has no single cause, but rather can result from a complex group of risk factors. People who begin drinking at an early age are at high risk of alcohol dependence or abuse.¹ The risk of alcohol dependence is higher for those with a parent who abused alcohol.² Furthermore, it is common for people with a mental health disorder, such as anxiety or depression, to abuse alcohol.³

For complete information, see:

1. Hingson RW, Heeren T, Winter MR. Age at drinking onset and alcohol dependence: age at onset, duration, and severity. *Arch Pediatr Adolesc Med.* 2006;160(7):739-746.
2. Rossow I, Keating P, Felix L, McCambridge J. Does parental drinking influence children's drinking? A systematic review of prospective cohort studies. *Addiction.* 2016;111(2):204-217.
3. Swendsen J, Conway KP, Degenhardt L, et al. Mental disorders as risk factors for substance use, abuse and dependence: results from the 10-year follow-up of the National Comorbidity Survey. *Addiction.* 2010;105(6):1117-1128.

Please see [Prescribing Information](#) and [Medication Guide](#). Review the [Medication Guide](#) with your patients.

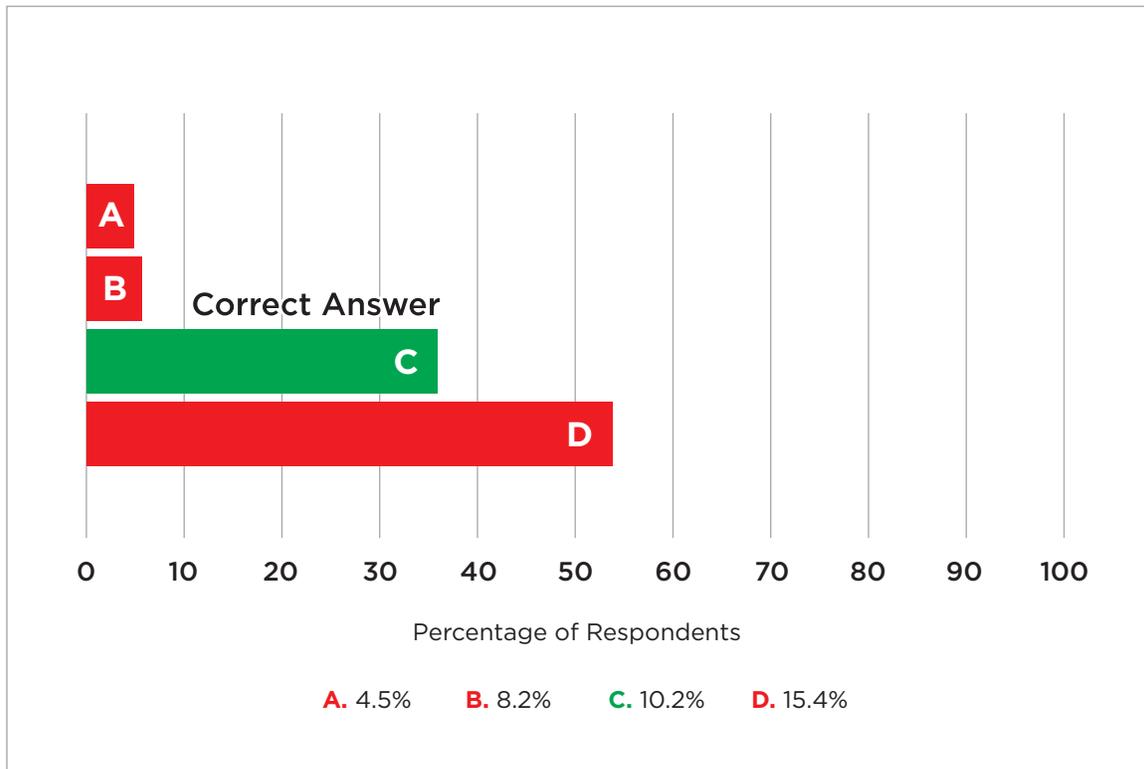


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Question 2 of 5: According to the 2009-2011 National Survey on Drug Use and Health, what proportion of excessive drinkers is also dependent on alcohol?

Finding: More than half of respondents overestimated the prevalence of alcohol dependence among excessive drinkers.



Explanation

According to a large epidemiologic survey of U.S. adults (N=138,100), 10.2% of respondents who identified as excessive drinkers met the criteria for alcohol dependence. The prevalence of alcohol dependence was significantly higher among excessive drinkers (10.2%) and binge drinkers (10.5%) than among non-binge drinkers (1.35%).

For complete information, see:

Esser MB, Hedden SL, Kanny D, Brewer RD, Gfroerer JC, Naimi TS. Prevalence of alcohol dependence among US adult drinkers, 2009-2011. *Prev Chronic Dis.* 2014;11:E206.

Further Reading: Substance Abuse and Mental Health Services Administration (SAMHSA). Screening, Brief Intervention, and Referral to Treatment (SBIRT). <https://www.samhsa.gov/sbirt>. Updated September 15, 2017.

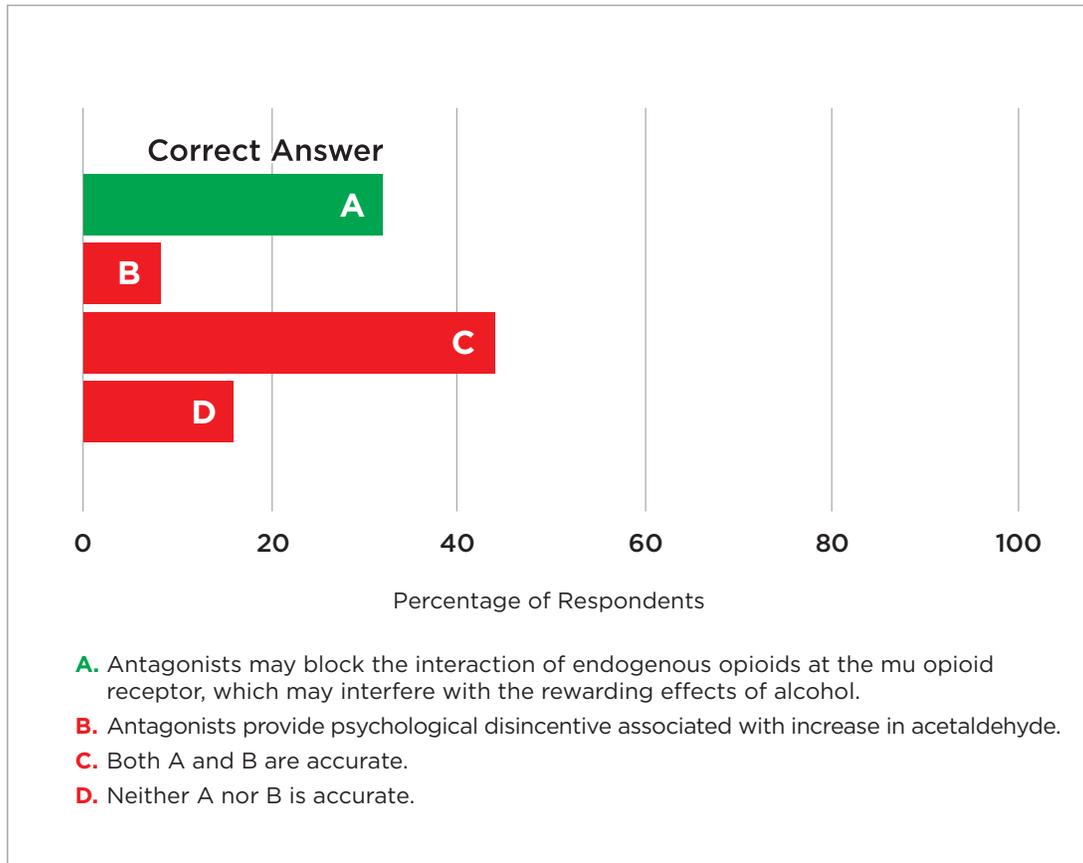


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Question 3 of 5: Which of the following statements describing antagonist therapy for alcohol dependence is most accurate?

Finding: Only about one-third of respondents appear to understand the mechanism by which antagonist therapy is believed to work in the treatment of alcohol dependence.



Explanation

The rewarding effects of alcohol are thought to be mediated via the release of endogenous opioids that facilitates mesolimbic dopaminergic activity. Research has shown that an opiate receptor antagonist blocks this response, reducing alcohol-induced dopaminergic activity in the nucleus accumbens.

For complete information, see:

Lukas SE, Lowen SB, Lindsey KP, et al. Extended-release naltrexone (XR-NTX) attenuates brain responses to alcohol cues in alcohol-dependent volunteers: a bold fMRI study. *Neuroimage*. 2013;78:176-185.

Further Reading: American Psychiatric Association. *Practice Guideline for the Pharmacological Treatment of Patients With Alcohol Use Disorder*. <https://psychiatryonline.org/doi/book/10.1176/appi.books.9781615371969>.

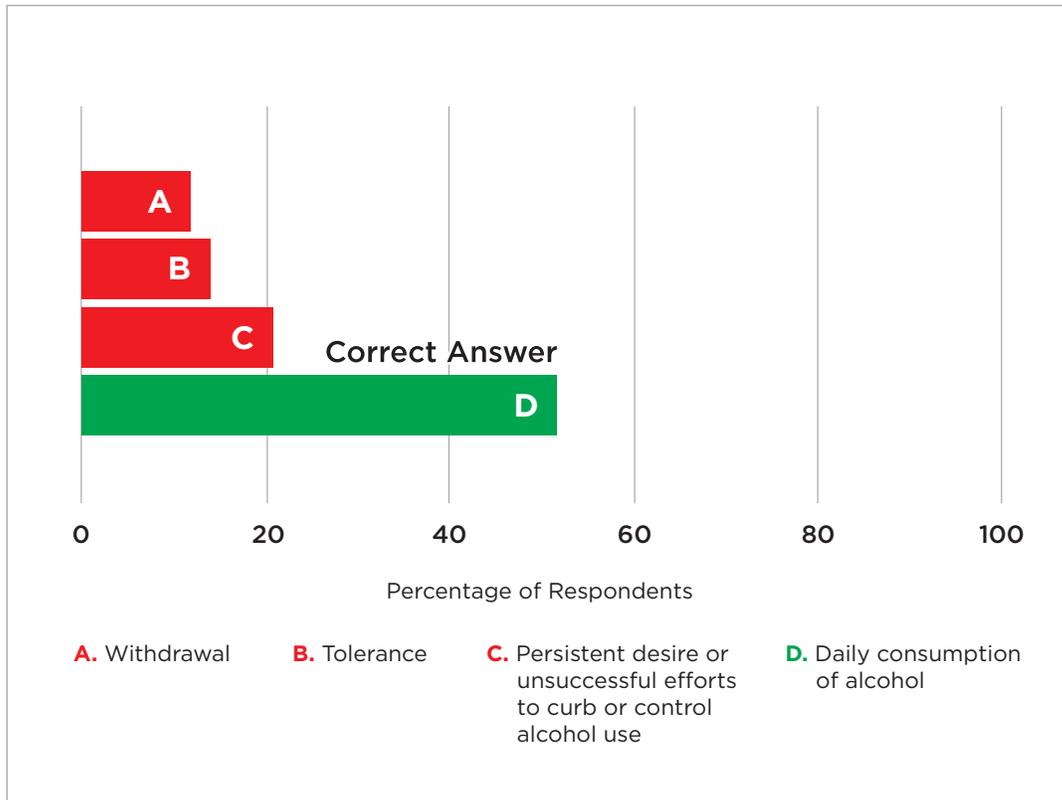


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Question 4 of 5: Which of the following is NOT a characteristic of alcohol dependence according to the *DSM-IV-TR* criteria?

Finding: Nearly half of respondents appear to not have a full understanding of the *DSM-IV-TR* criteria for alcohol dependence.



Explanation

DSM-IV-TR defines alcohol dependence as a maladaptive pattern of alcohol abuse leading to clinically significant impairment or distress, as manifested by 3 (or more) of the following occurring in the same 12-month period:

1. Tolerance
2. Withdrawal
3. Taking the substance in larger amounts of longer than intended
4. Persistent desire or unsuccessful efforts to curb or control use
5. Excessive time spent obtaining, using, or recovering from use
6. Important activities are given up or reduced because of use
7. Continued use despite acknowledged physical or psychological problem due to use

Although daily consumption of alcohol may warrant further discussion with a patient, it is not in itself a characteristic of alcohol dependence.

DSM-IV-TR, Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision.

For complete information, see:

American Psychiatric Association. *Diagnostic and Statistical Manual of Mental Disorders*. 4th ed. Text Revision. Washington, DC: American Psychiatric Association; 2000.

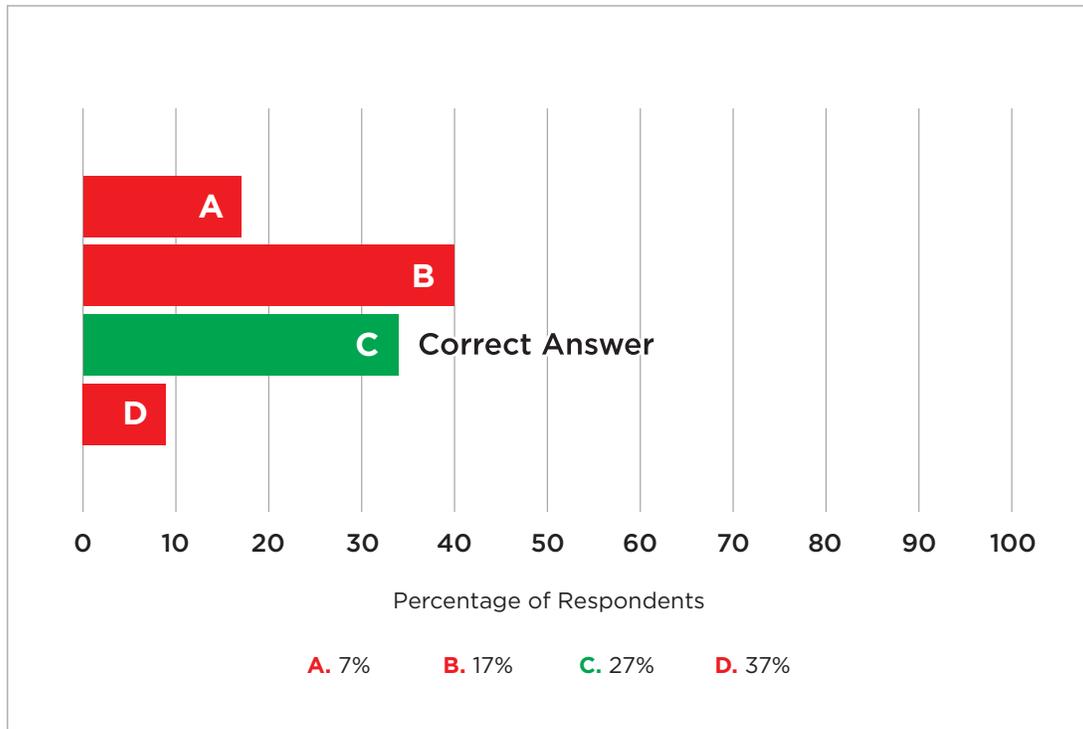


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Question 5 of 5: According to the 2015 National Survey on Drug Use and Health, how many adults reported that they engaged in binge drinking in the past month?

Finding: Nearly 60% of respondents underestimated the proportion of adults who reported binge drinking. (Note that patient self-reports may underrepresent actual prevalence).



Explanation

In 2015, 26.9% of people aged 18 or older reported that they engaged in binge drinking in the past month, while 7.0% reported that they engaged in heavy alcohol use in the same time frame.¹ The National Institute on Alcohol Abuse and Alcoholism defines binge drinking as a pattern of drinking that brings blood alcohol concentration levels to 0.08 g/dL. This typically occurs after 4 drinks for women and 5 drinks for men.²

For complete information, see:

1. Alcohol facts and statistics. National Institute on Alcohol Abuse and Alcoholism Web site. Published February 2017. <https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/alcohol-facts-and-statistics>. Accessed April 27, 2017.
2. Drinking levels defined. National Institute on Alcohol Abuse and Alcoholism Web site. <https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking>. Accessed March 27, 2017.

Further Reading: National Institute on Alcohol Abuse and Alcoholism (NIAAA). Drinking Levels Defined. <https://www.niaaa.nih.gov/alcohol-health/overview-alcohol-consumption/moderate-binge-drinking>.

For more information on the treatment of alcohol dependence, view a [practice guideline](#) from the American Psychiatric Association.

IMPORTANT SAFETY INFORMATION

INDICATIONS

VIVITROL[®] (naltrexone for extended-release injectable suspension) is indicated for:

- Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- Prevention of relapse to opioid dependence, following opioid detoxification.
- VIVITROL should be part of a comprehensive management program that includes psychosocial support.

CONTRAINDICATIONS

VIVITROL is contraindicated in patients:

- Receiving opioid analgesics
- With current physiologic opioid dependence
- In acute opioid withdrawal
- Who have failed the naloxone challenge test or have a positive urine screen for opioids
- Who have exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent

WARNINGS AND PRECAUTIONS

Vulnerability to Opioid Overdose:

- After opioid detoxification, patients are likely to have a reduced tolerance to opioids. VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration. As the blockade wanes and eventually dissipates completely, use of previously tolerated doses of opioids could result in potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc.).
- Cases of opioid overdose with fatal outcomes have been reported in patients who used opioids at the end of a dosing interval, after missing a scheduled dose, or after discontinuing treatment. Patients and caregivers should be told of this increased sensitivity to opioids and the risk of overdose.
- Although VIVITROL is a potent antagonist with a prolonged pharmacological effect, the blockade produced by VIVITROL is surmountable. The plasma concentration of exogenous opioids attained immediately following their acute administration may be sufficient to overcome the competitive receptor blockade. This poses a potential risk to individuals who attempt, on their own, to overcome the blockade by administering large amounts of exogenous opioids.
- Any attempt by a patient to overcome the VIVITROL blockade by taking opioids may lead to fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.

Injection Site Reactions:

- VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising, or pruritus; however, in some cases injection site reactions may be very severe.
- Injection site reactions not improving may require prompt medical attention, including, in some cases, surgical intervention.
- Inadvertent subcutaneous/adipose layer injection of VIVITROL may increase the likelihood of severe injection site reactions.
- Select proper needle size for patient body habitus, and use only the needles provided in the carton.
- Patients should be informed that any concerning injection site reactions should be brought to the attention of their healthcare provider.

Precipitation of Opioid Withdrawal:

- When withdrawal is precipitated abruptly by administration of an opioid antagonist to an opioid-dependent patient, the resulting withdrawal syndrome can be severe. Some cases of withdrawal symptoms have been severe enough to require hospitalization, and in some cases, management in the ICU.
- To prevent occurrence of precipitated withdrawal, opioid-dependent patients, including those being treated for alcohol dependence, should be opioid-free (including tramadol) before starting VIVITROL treatment:

- An opioid-free interval of a minimum of 7-10 days is recommended for patients previously dependent on short-acting opioids.
- Patients transitioning from buprenorphine or methadone may be vulnerable to precipitated withdrawal for as long as two weeks.
- If a more rapid transition from agonist to antagonist therapy is deemed necessary and appropriate by the healthcare provider, monitor the patient closely in an appropriate medical setting where precipitated withdrawal can be managed.
- Patients should be made aware of the risk associated with precipitated withdrawal and be encouraged to give an accurate account of last opioid use.

Hepatotoxicity:

- Cases of hepatitis and clinically significant liver dysfunction have been observed in association with VIVITROL. Warn patients of the risk of hepatic injury; advise them to seek help if experiencing symptoms of acute hepatitis. Discontinue use of VIVITROL in patients who exhibit acute hepatitis symptoms.

Depression and Suicidality:

- Alcohol- and opioid-dependent patients taking VIVITROL should be monitored for depression or suicidal thoughts. Alert families and caregivers to monitor and report the emergence of symptoms of depression or suicidality.

When Reversal of VIVITROL Blockade Is Required for Pain Management:

- For VIVITROL patients in emergency situations, suggestions for pain management include regional analgesia or use of non-opioid analgesics. If opioid therapy is required to reverse the VIVITROL blockade, patients should be closely monitored by trained personnel in a setting staffed and equipped for CPR.

Eosinophilic Pneumonia:

- Cases of eosinophilic pneumonia requiring hospitalization have been reported. Warn patients of the risk of eosinophilic pneumonia and to seek medical attention if they develop symptoms of pneumonia.

Hypersensitivity Reactions:

- Patients should be warned of the risk of hypersensitivity reactions, including anaphylaxis.

Intramuscular Injections:

- As with any IM injection, VIVITROL should be administered with caution to patients with thrombocytopenia or any coagulation disorder.

Alcohol Withdrawal:

- Use of VIVITROL does not eliminate nor diminish alcohol withdrawal symptoms.

ADVERSE REACTIONS

- Serious adverse reactions that may be associated with VIVITROL therapy in clinical use include severe injection site reactions, eosinophilic pneumonia, serious allergic reactions, unintended precipitation of opioid withdrawal, accidental opioid overdose, and depression and suicidality.
- The adverse events seen most frequently in association with VIVITROL therapy for alcohol dependence (ie, those occurring in $\geq 5\%$ and at least twice as frequently with VIVITROL than placebo) include nausea, vomiting, injection site reactions (including induration, pruritus, nodules, and swelling), muscle cramps, dizziness or syncope, somnolence or sedation, anorexia, decreased appetite or other appetite disorders.
- The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients (ie, those occurring in $\geq 2\%$ and at least twice as frequently with VIVITROL than placebo) were hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

You are encouraged to report side effects to the FDA.

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

Please see Prescribing Information and Medication Guide. Review the Medication Guide with your patients.



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