Key Techniques to Reduce Severe Injection Site Reactions
VIVITROL® (naltrexone for extended-release injectable suspension)
Intramuscular Injection

- **Use appropriate VIVITROL needle to ensure the injection reaches the gluteal muscle**
  Select the 2-inch needle for patients with more subcutaneous adipose tissue. Select the 1.5-inch needle for patients with less subcutaneous adipose tissue. Use either needle for patients of average body habitus.

- **Use aseptic technique when administering VIVITROL intramuscularly**
  Using a circular motion, clean the injection site with the alcohol swab. Leave it to dry before injecting. Do not touch this area again before giving the injection.

- **Use proper deep intramuscular injection technique into gluteal muscle**
  VIVITROL must NOT be given intravenously, subcutaneously, or into adipose tissue. Inadvertent subcutaneous injection of VIVITROL may increase the likelihood of severe injection site reactions.

  1. Administer the suspension by deep intramuscular injection into the upper, outer quadrant of a gluteal muscle, alternating buttocks per monthly injection. **Remember to aspirate for blood before injection.**

  2. If blood aspirates or the needle clogs, do not inject. Change to the spare needle provided in the carton and administer into an adjacent site in the same gluteal region, again aspirating for blood before injection.

  3. Inject the suspension in a smooth and continuous motion.

A Patient Counseling Tool is available to counsel your patients prior to administration about the serious risks associated with VIVITROL.*

The above information is a selection of key Safety Information relating to the VIVITROL injection. Please refer to the Directions for Use and Prescribing Information for the complete Safety Information.*

*The Prescribing Information and Patient Counseling Tool are available from www.vivitrolrems.com or by calling 1-800-VIVITROL, Option #1. The Prescribing Information is also included in the VIVITROL Kit.
RISK EVALUATION AND MITIGATION STRATEGY (REMS)

A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug product and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

VIVITROL, when used as part of a comprehensive management program, is indicated for the following:

- Treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL
- Prevention of relapse to opioid dependence following opioid detoxification

Providers and patients should be aware of the following risks of VIVITROL:

- Risk of opioid overdose
- Severe injection site reactions
- Precipitation of opioid withdrawal during initiation and re-initiation of VIVITROL
- Hepatotoxicity
- Patients may not feel the therapeutic effects of opioid-containing medicines for pain, cough or cold, or diarrhea while taking VIVITROL.

Materials for Healthcare Providers

- Dear Healthcare Provider Letter
- Patient Counseling Tool for Providers
- Important Injection Safety Information Poster

To order any of the healthcare provider materials, call:

1-800-848-4876

- Dear Healthcare Provider Letter
- Patient Counseling Tool for Providers
- Important Injection Safety Information Poster
- Patient Wallet Card
- Patient Safety Bracelet
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JUDITH A RACOOSIN
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