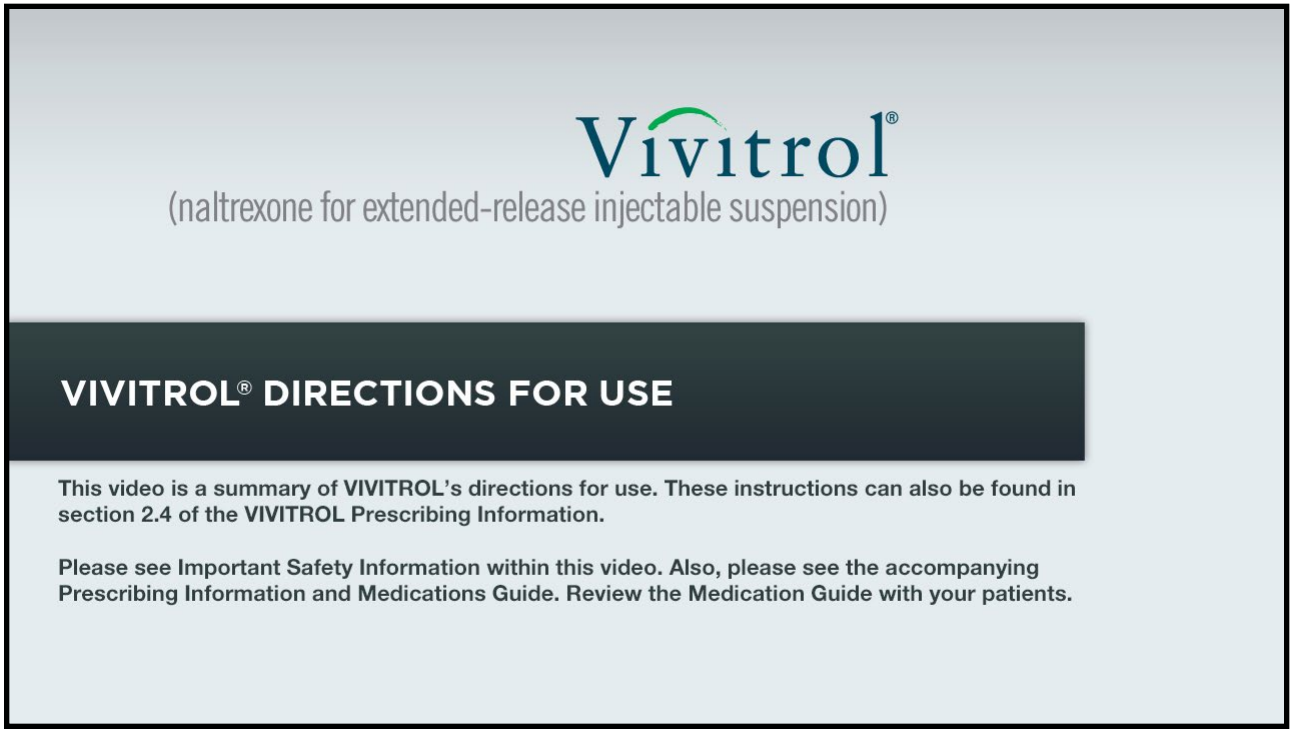
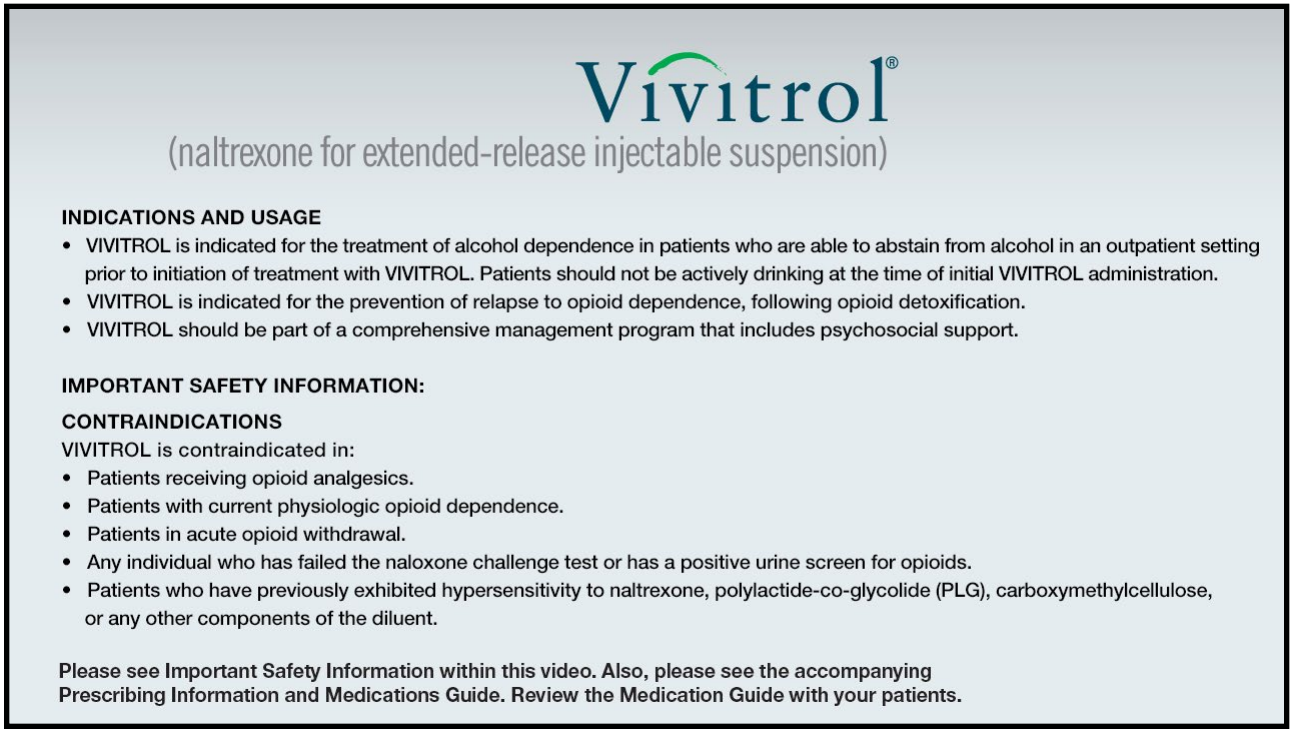


FRAME 1

VO:
VIVITROL® DIRECTIONS FOR USE

This video is a summary of VIVITROL's directions for use. These instructions can also be found in section 2.4 of the VIVITROL Prescribing Information.

Please see Important Safety Information within this video. Also, please see the accompanying Prescribing Information and Medications Guide. Review the Medication Guide with your patients.



FRAME 2

VO:

INDICATIONS AND USAGE

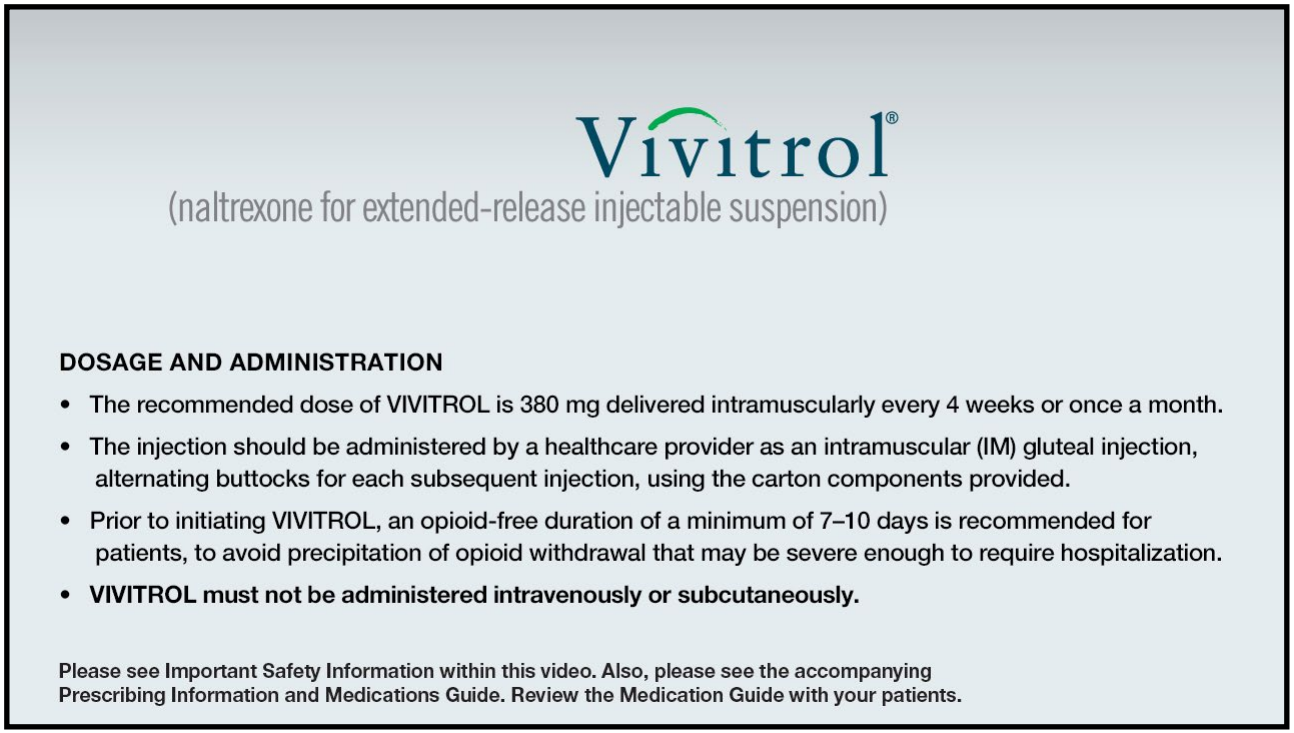
- VIVITROL is indicated for the treatment of alcohol dependence in patients who are able to abstain from alcohol in an outpatient setting prior to initiation of treatment with VIVITROL. Patients should not be actively drinking at the time of initial VIVITROL administration.
- VIVITROL is indicated for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

IMPORTANT SAFETY INFORMATION:

CONTRAINDICATIONS

VIVITROL is contraindicated in:

- Patients receiving opioid analgesics.
- Patients with current physiologic opioid dependence.
- Patients in acute opioid withdrawal.
- Any individual who has failed the naloxone challenge test or has a positive urine screen for opioids.
- Patients who have previously exhibited hypersensitivity to naltrexone, polylactide-co-glycolide (PLG), carboxymethylcellulose, or any other components of the diluent.

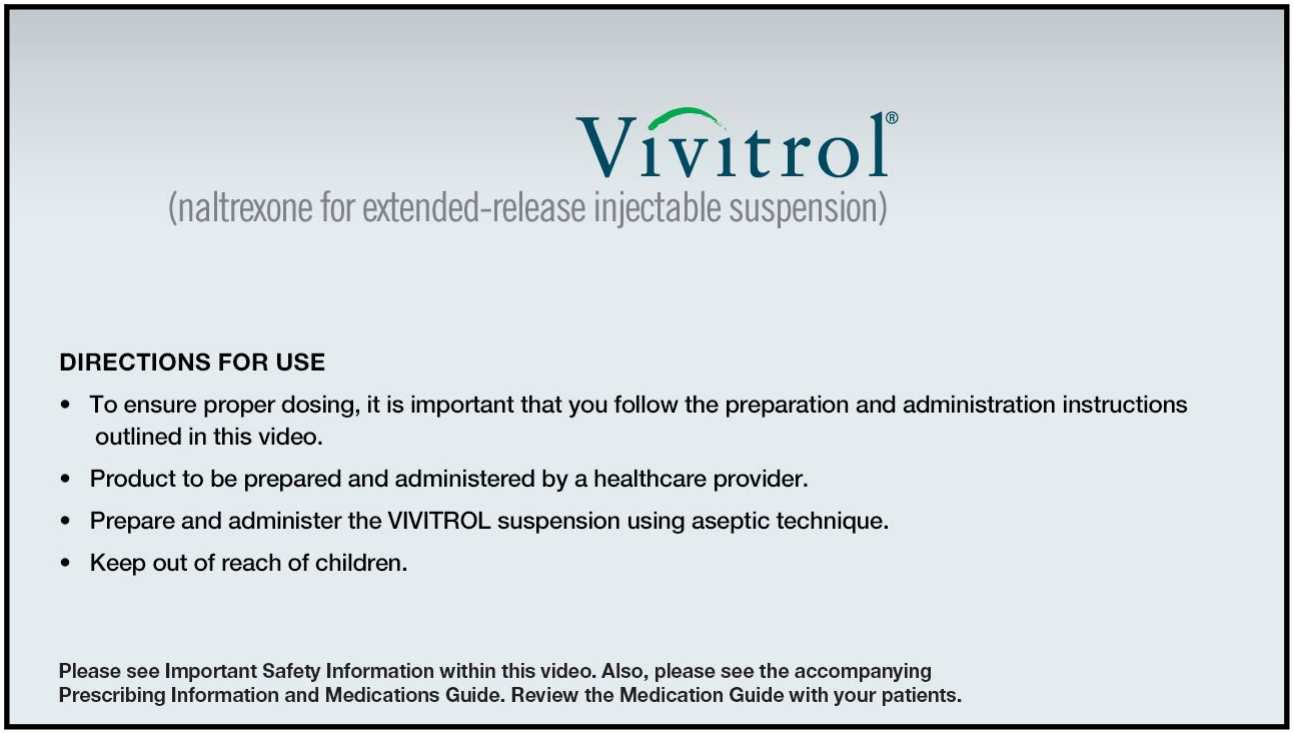


FRAME 3

VO:

DOSAGE AND ADMINISTRATION

- The recommended dose of VIVITROL is 380 mg delivered intramuscularly every 4 weeks or once a month.
- The injection should be administered by a healthcare provider as an intramuscular (IM) gluteal injection, alternating buttocks for each subsequent injection, using the carton components provided.
- Prior to initiating VIVITROL, an opioid-free duration of a minimum of 7–10 days is recommended for patients, to avoid precipitation of opioid withdrawal that may be severe enough to require hospitalization.
- **VIVITROL must not be administered intravenously or subcutaneously.**

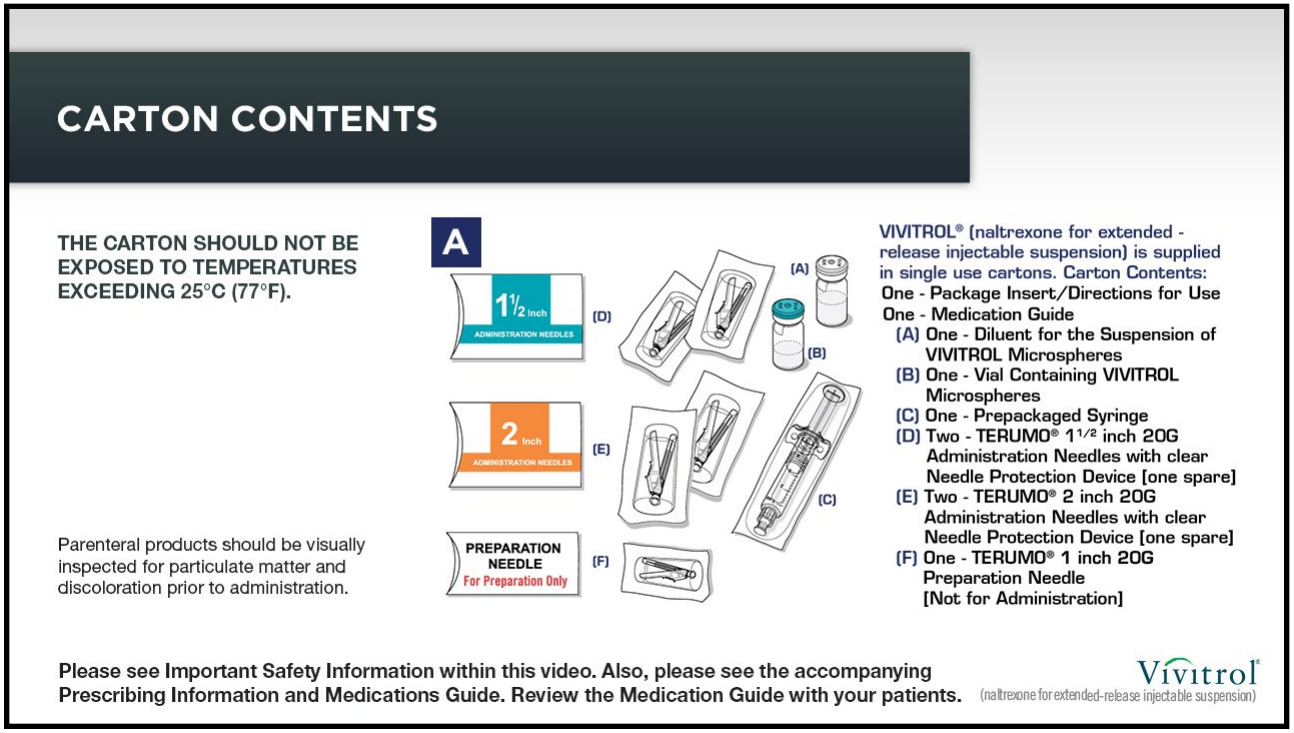


FRAME 4

VO:

DIRECTIONS FOR USE

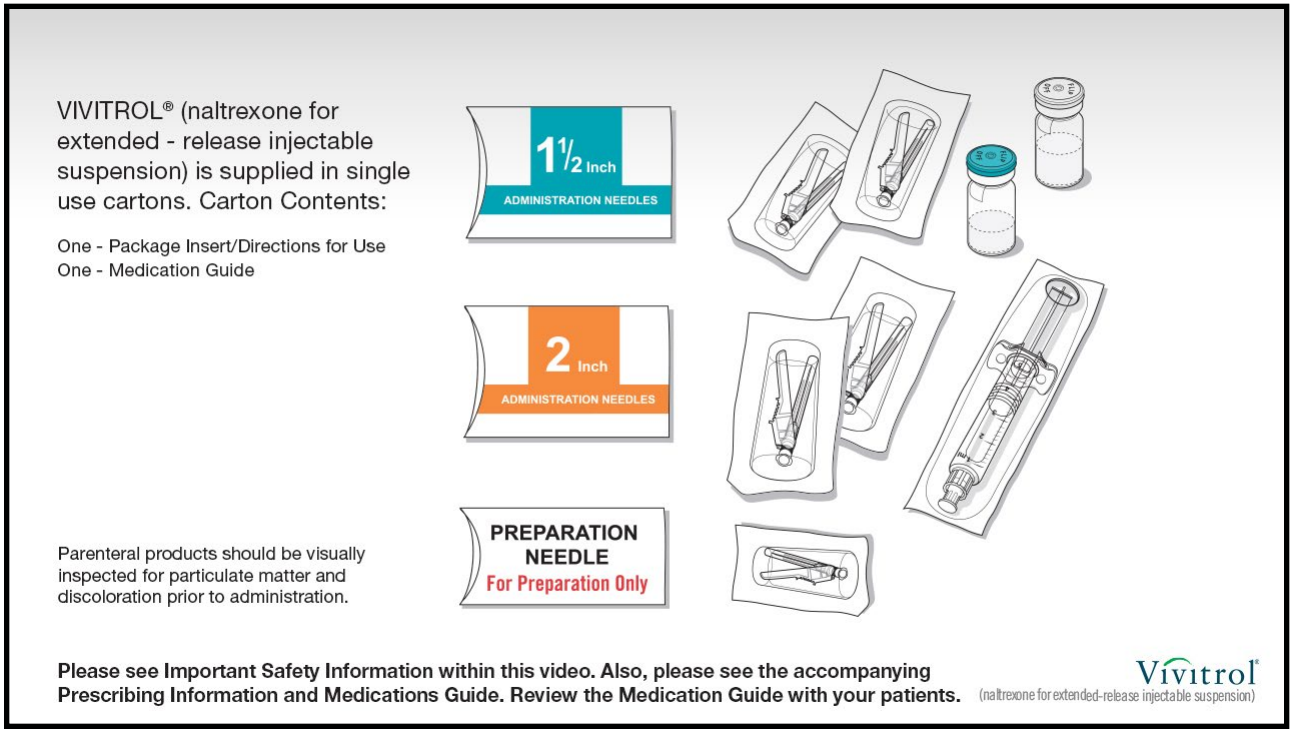
- To ensure proper dosing, it is important that you follow the preparation and administration instructions outlined in this video.
- Product to be prepared and administered by a healthcare provider.
- Prepare and administer the VIVITROL suspension using aseptic technique.
- Keep out of reach of children.



FRAME 5

VO:

- VIVITROL (naltrexone for extended-release injectable suspension) is supplied in single-use cartons
- VIVITROL must be suspended only in the diluent supplied in the carton and must be administered only with one of the administration needles supplied in the carton.
- The microspheres, diluent, preparation needle, and an administration needle with needle protection device are required for preparation and administration.
- The entire carton should be stored in the refrigerator at 2 to 8 degrees Celsius or 36 to 46 degrees Fahrenheit. Unrefrigerated, VIVITROL microspheres can be stored at temperatures not exceeding 25 degrees Celsius (77 degrees Fahrenheit) for no more than 7 days prior to administration. Do not expose unrefrigerated product to temperatures above 25 degrees Celsius (77 degrees Fahrenheit). VIVITROL should not be frozen.



FRAME 6

VO:
Parenteral products should be visually inspected for particulate matter and discoloration prior to administration.

Carton contents include one package insert with directions for use and one medication guide.

Do not susbtitute any other components for the components of the carton.

FRAME 7

VO:
It also includes one diluent for the suspension of VIVITROL Microspheres

FRAME 8

VO:
One vial containing
VIVITROL Microspheres

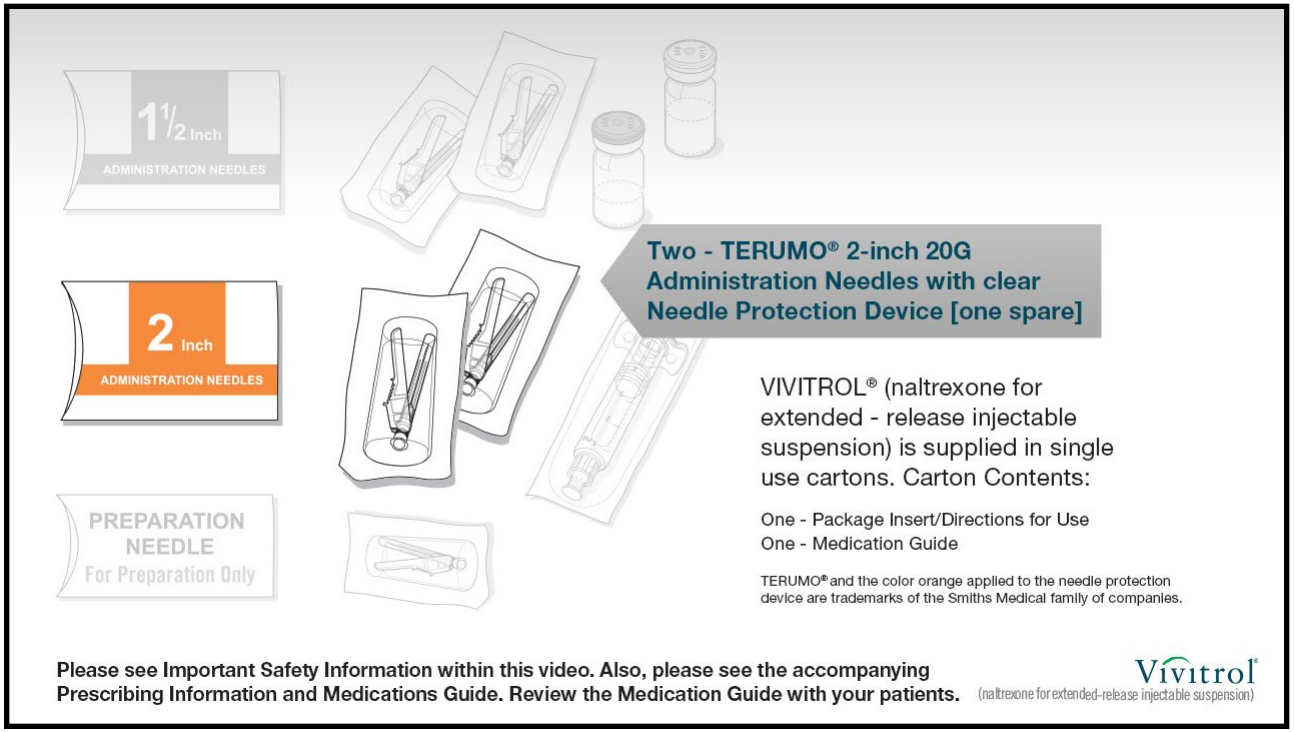
FRAME 9

VO:
One prepackaged syringe

FRAME 10

VO:
Two TERUMO® one and one half inch 20-gauge Administration Needles with clear Needle Protection Device have been provided to accommodate varying patient body habitus.

For very lean patients, the 1 1/2-inch needle may be appropriate to prevent the needle contacting the periosteum.



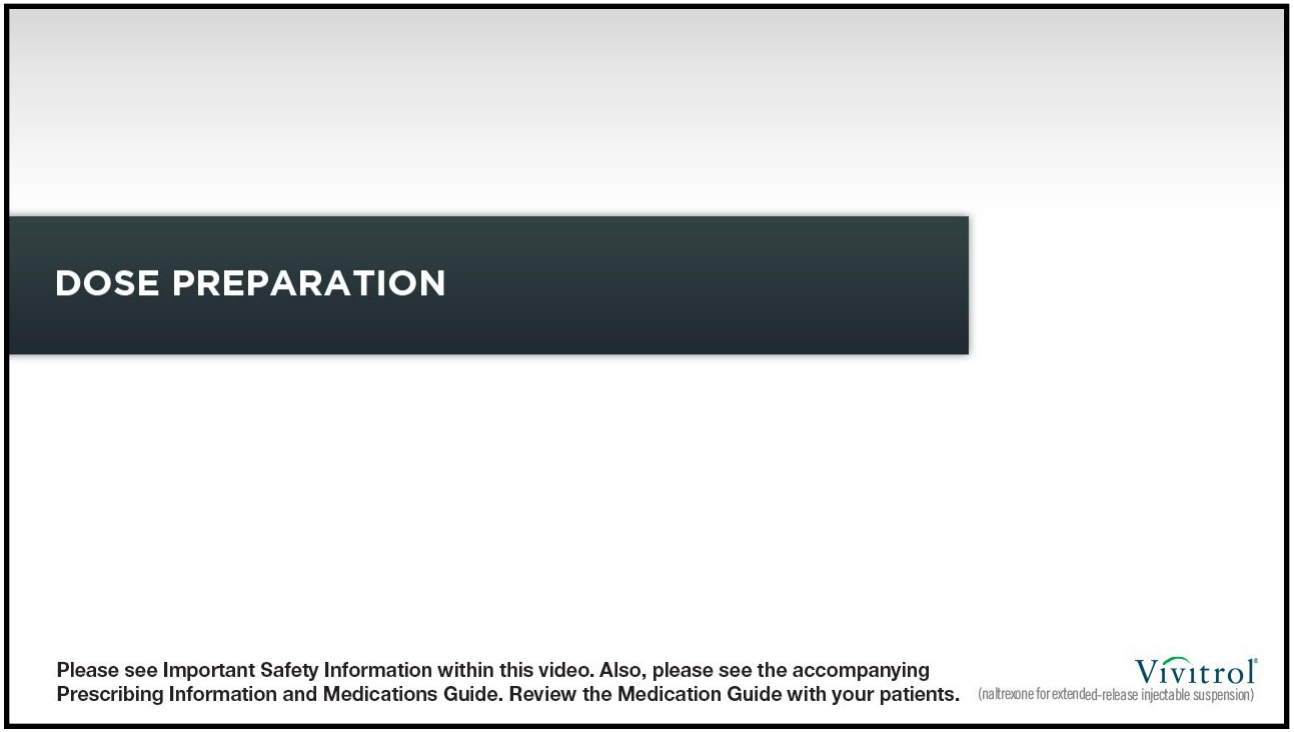
FRAME 11

VO:

- Two TERUMO® two-inch 20-gauge Administration Needles with clear Needle Protection Device have been provided to accommodate varying patient body habitus.
- For patients with a larger amount of subcutaneous tissue overlying the gluteal muscle, the administering healthcare provider may utilize the supplied 2-inch needle with needle protection device to help ensure that the injectate reaches the intramuscular mass.
- Either needle may be used for patients with average body habitus.
- A spare administration needle of each size is provided in case of clogging.

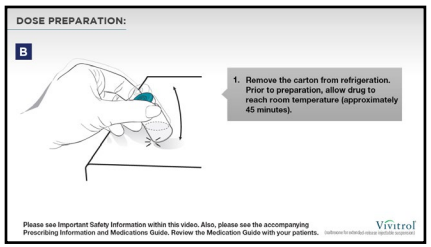
FRAME 12

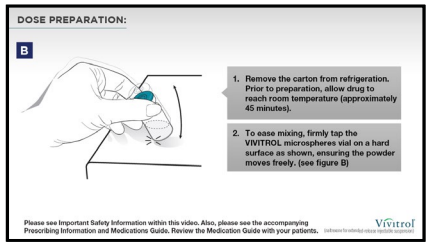
VO:
And one TERUMO® one-inch 20-gauge Preparation Needle. This is not for administration.

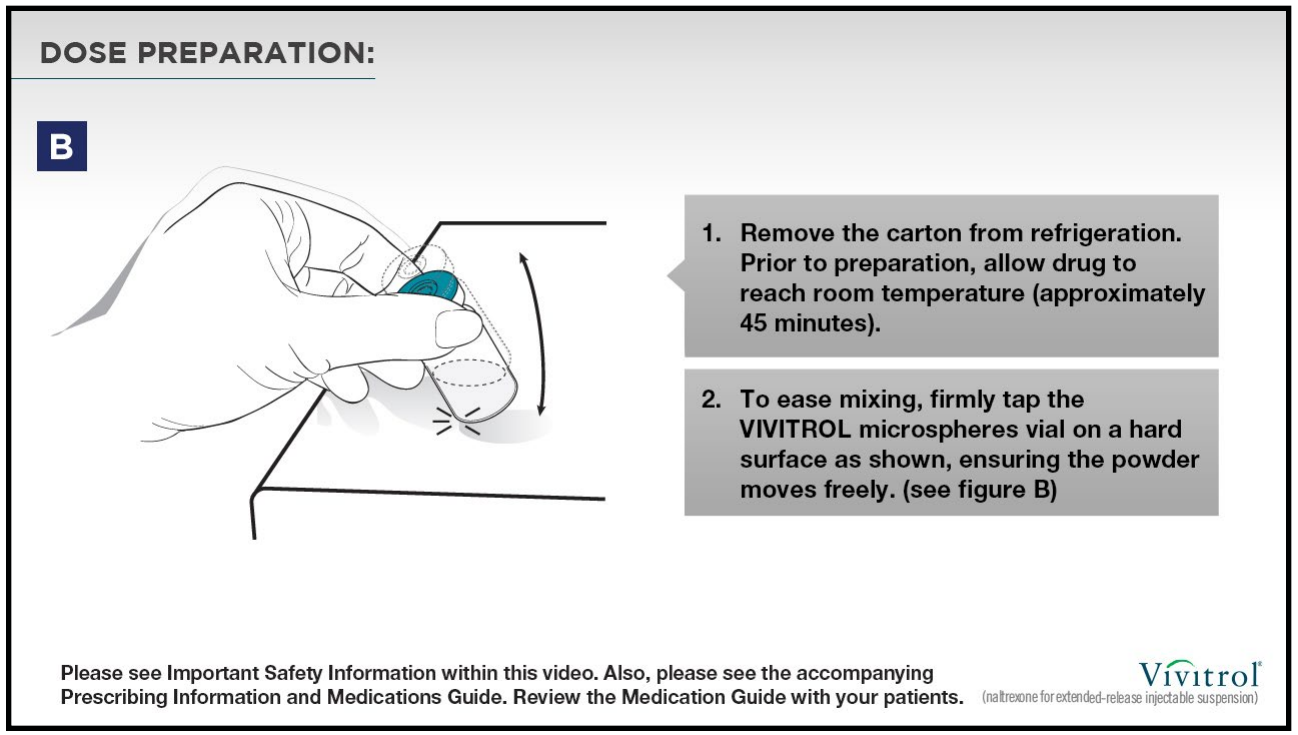


FRAME 13

VO:
DOSE PREPARATION



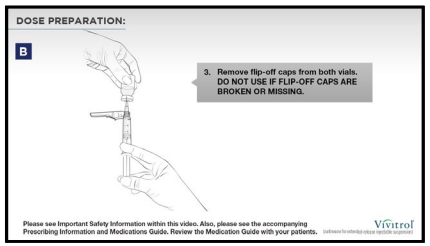


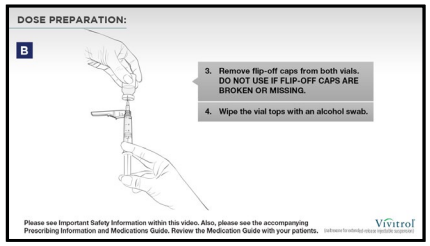


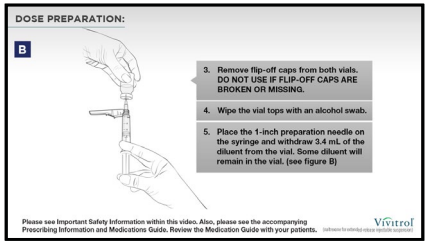
FRAME 14

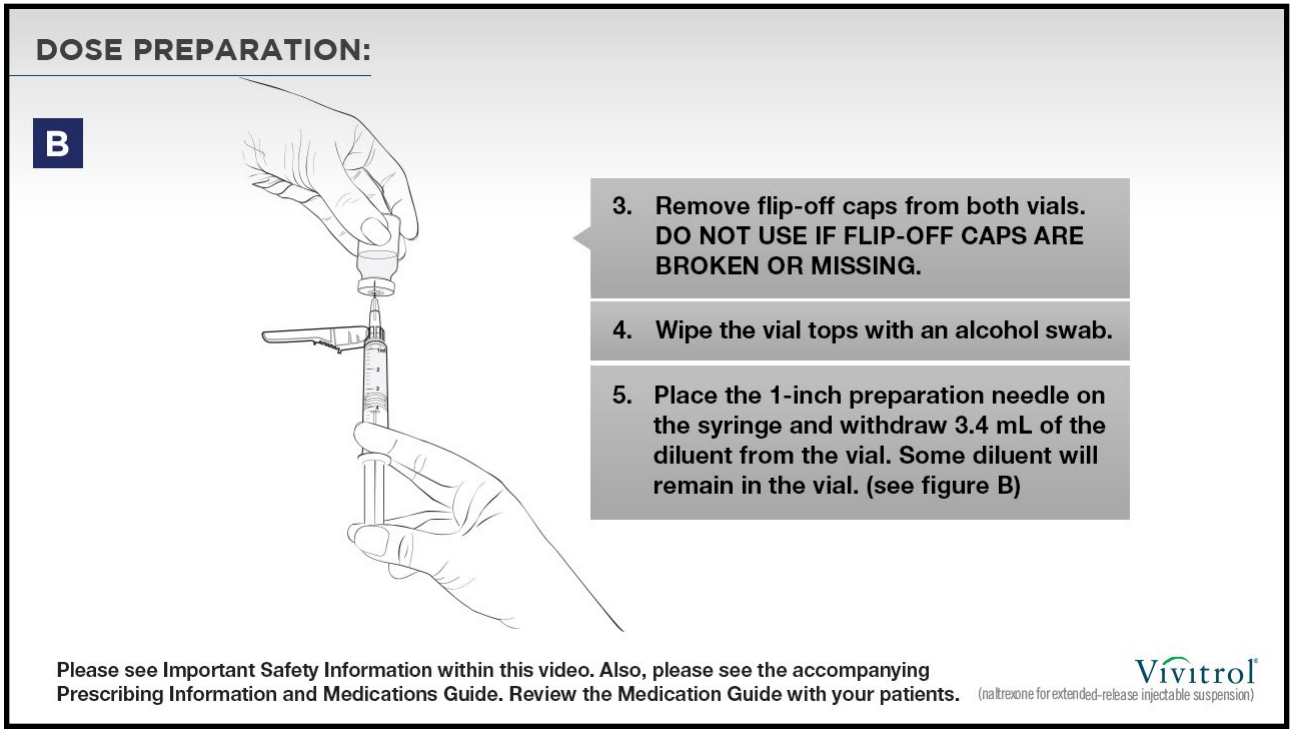
VO:
For dose preparation, remove the carton from refrigeration. Prior to preparation, allow drug to reach room temperature. This takes approximately 45 minutes.

To ease mixing, firmly tap the VIVITROL microspheres vial on a hard surface as shown, ensuring the powder moves freely. (see figure B)







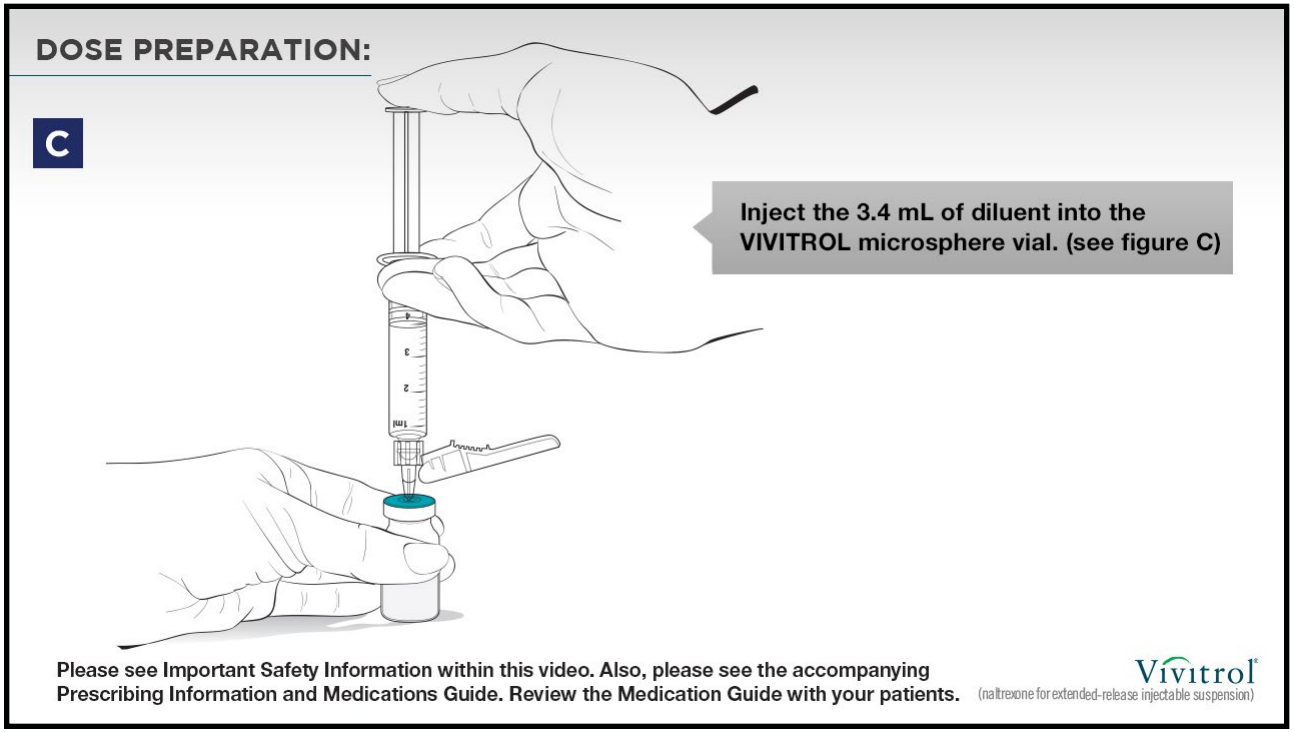


FRAME 15

VO:
Remove flip-off caps from both vials.
DO NOT USE IF FLIP-OFF CAPS ARE BROKEN OR MISSING.

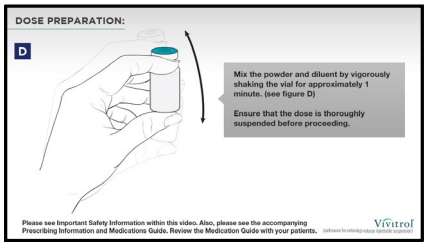
Wipe the vial tops with an alcohol swab.

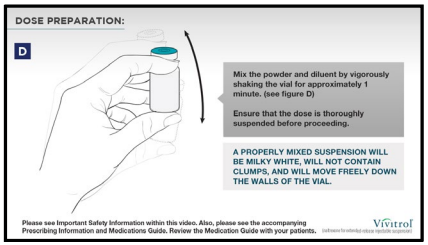
Then place the 1-inch preparation needle on the syringe and withdraw 3.4 milliliters of the diluent from the vial. Some diluent will remain in the vial. (see figure B)

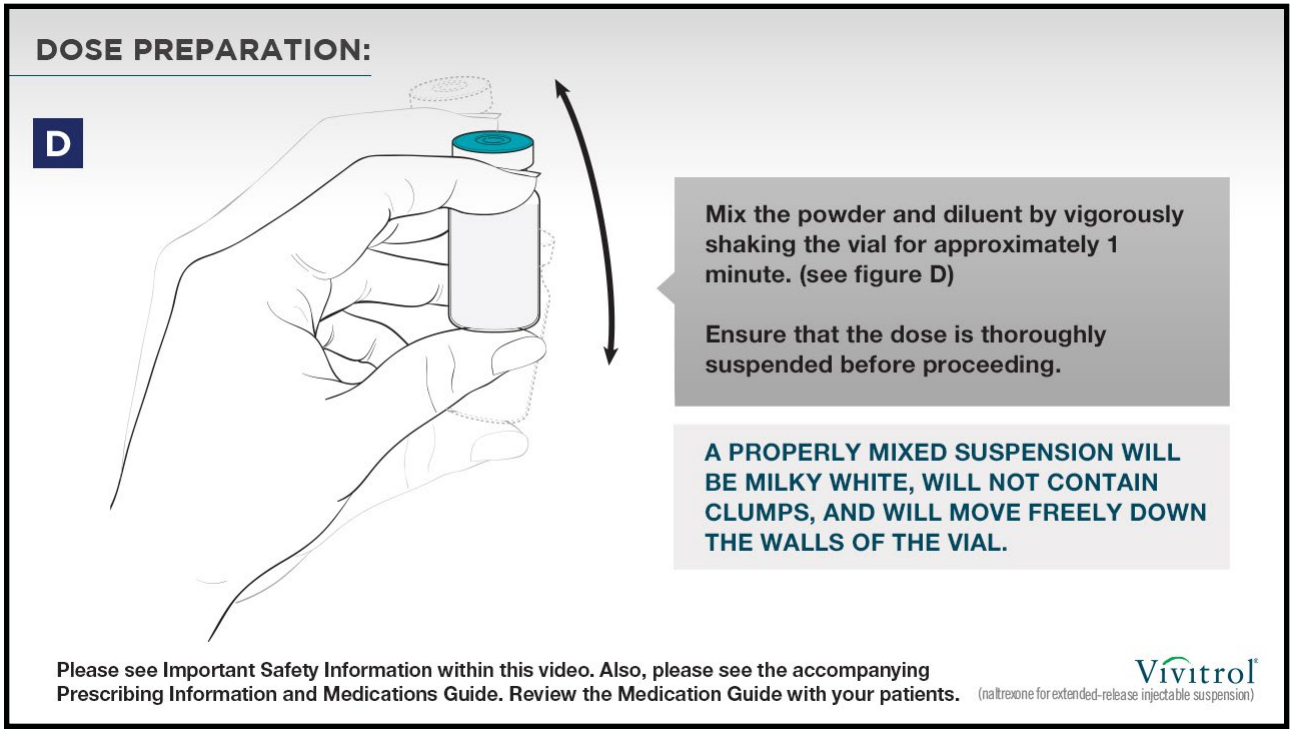


FRAME 16

VO:
Inject the 3.4 milliliters of diluent into the VIVITROL microsphere vial. (see figure C)





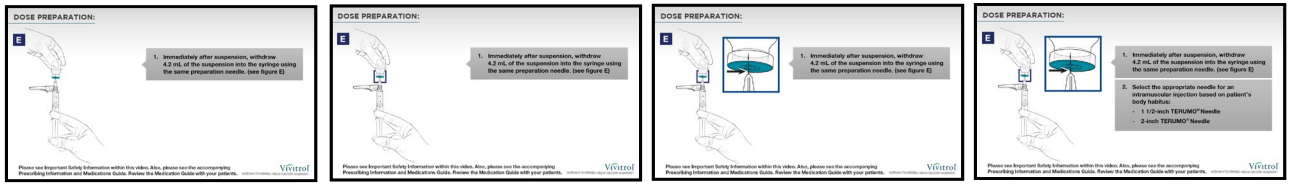


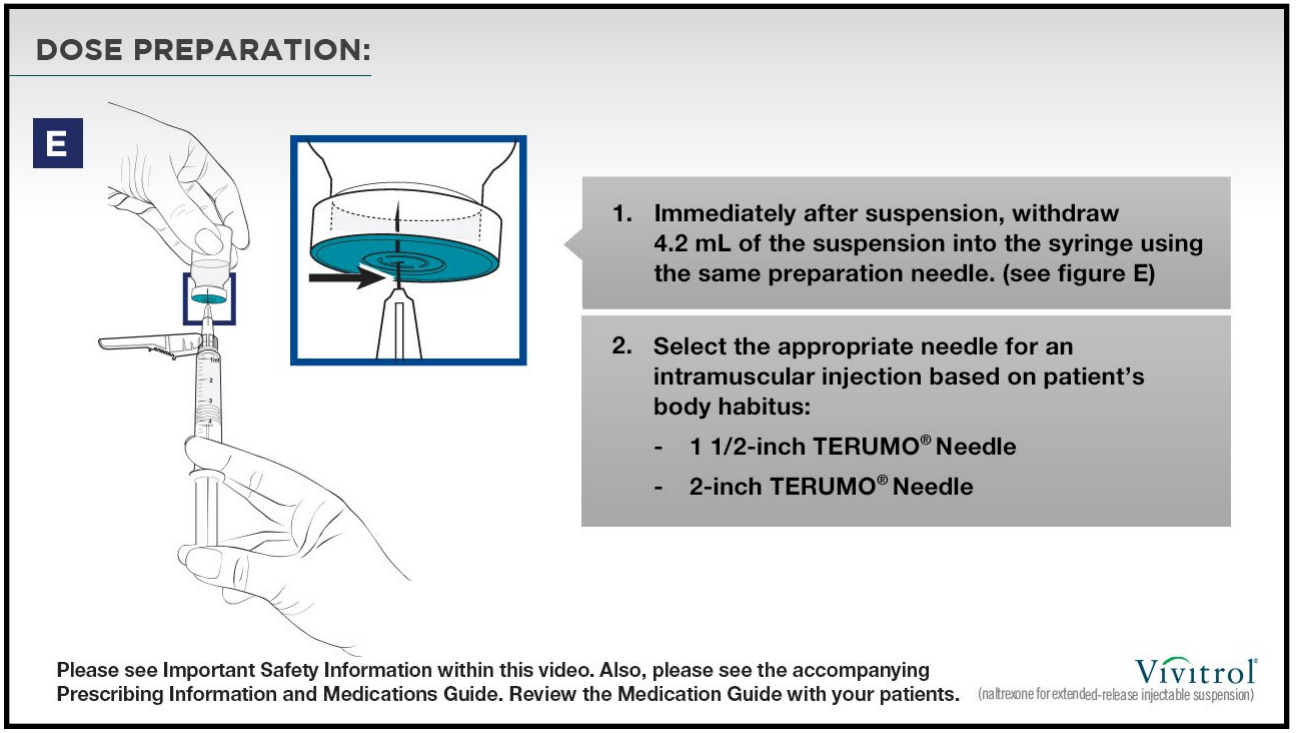
FRAME 17

VO:
Mix the powder and diluent by vigorously shaking the vial for approximately 1 minute. (see figure D)

Ensure that the dose is thoroughly suspended before proceeding.

A PROPERLY MIXED SUSPENSION WILL BE MILKY WHITE, WILL NOT CONTAIN CLUMPS, AND WILL MOVE FREELY DOWN THE WALLS OF THE VIAL.





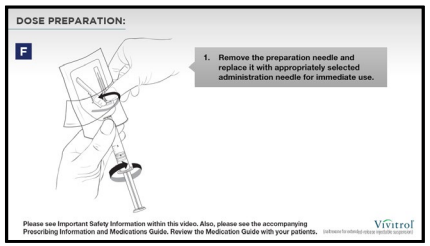
FRAME 18

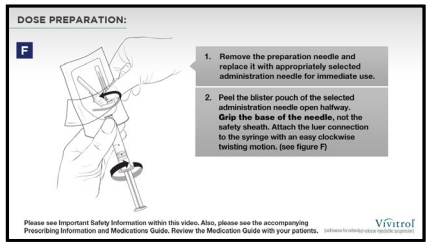
VO:

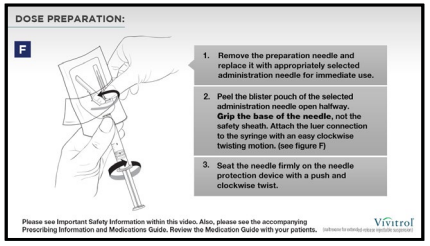
1. Immediately after suspension, withdraw 4.2 milliliters of the suspension into the syringe using the same preparation needle. (see figure E)

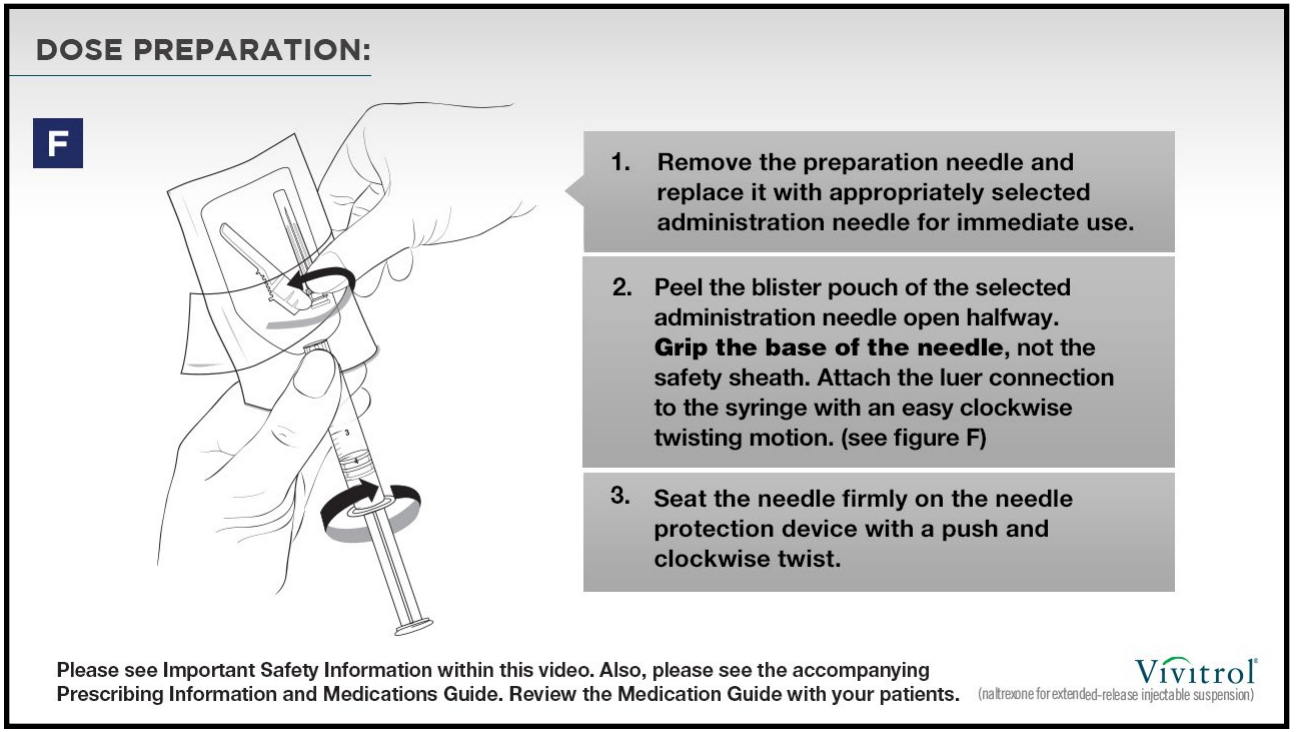
---

2. Select the appropriate needle for an intramuscular injection based on patient's body habitus:
    - 1 1/2-inch TERUMO® Needle
    - 2-inch TERUMO® Needle







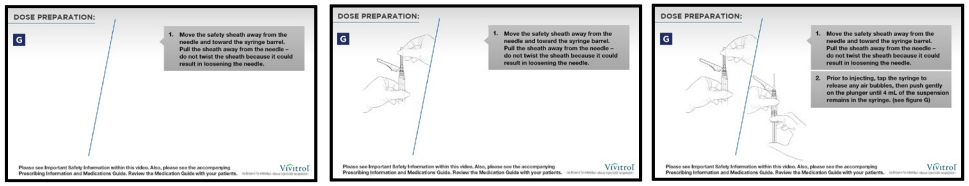


FRAME 19

VO:
Then remove the preparation needle and replace it with the appropriately selected administration needle for immediate use.

Peel the blister pouch of the selected administration needle open halfway. **Grip the base of the needle**, not the safety sheath. Attach the luer connection to the syringe with an easy clockwise twisting motion. (see figure F)

Next, seat the needle firmly on the needle protection device with a push and clockwise twist.



DOSE PREPARATION:

G

1. Move the safety sheath away from the needle and toward the syringe barrel. Pull the sheath away from the needle – do not twist the sheath because it could result in loosening the needle.

2. Prior to injecting, tap the syringe to release any air bubbles, then push gently on the plunger until 4 mL of the suspension remains in the syringe. (see figure G)

THE SUSPENSION IS NOW READY FOR IMMEDIATE ADMINISTRATION.

Please see Important Safety Information within this video. Also, please see the accompanying Prescribing Information and Medications Guide. Review the Medication Guide with your patients.

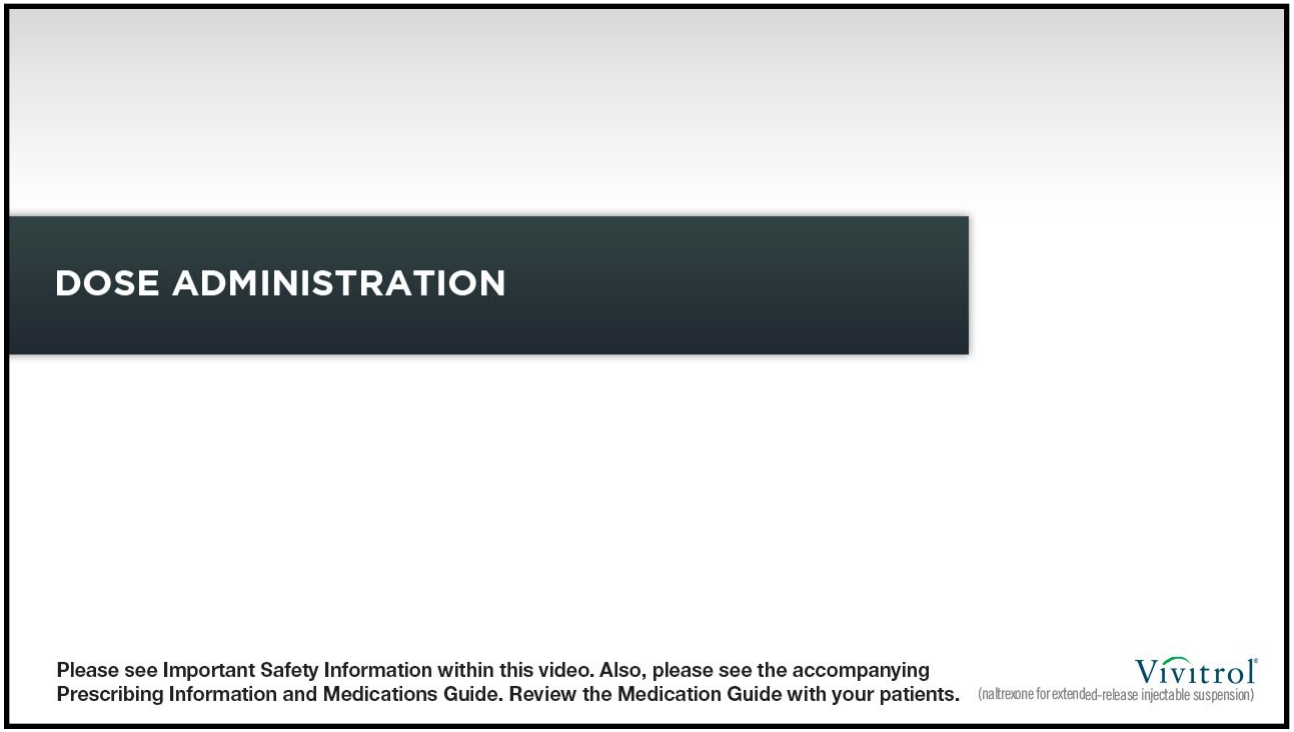
Vivitrol® (naltrexone for extended-release injectable suspension)

FRAME 20

VO:
Move the safety sheath away from the needle and toward the syringe barrel. Pull the sheath away from the needle – do not twist the sheath because it could result in loosening the needle.

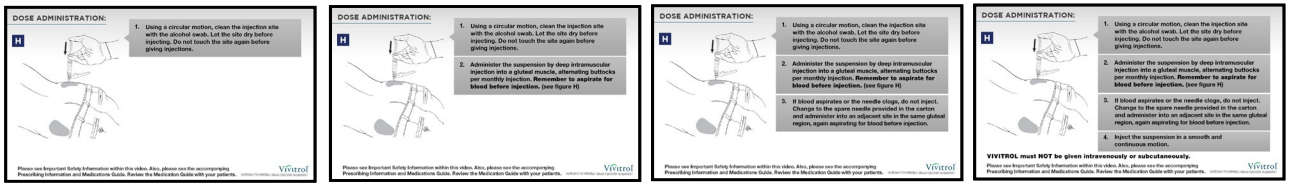
Prior to injecting, tap the syringe to release any air bubbles, then push gently on the plunger until 4 milliliters of the suspension remains in the syringe. (see figure G)

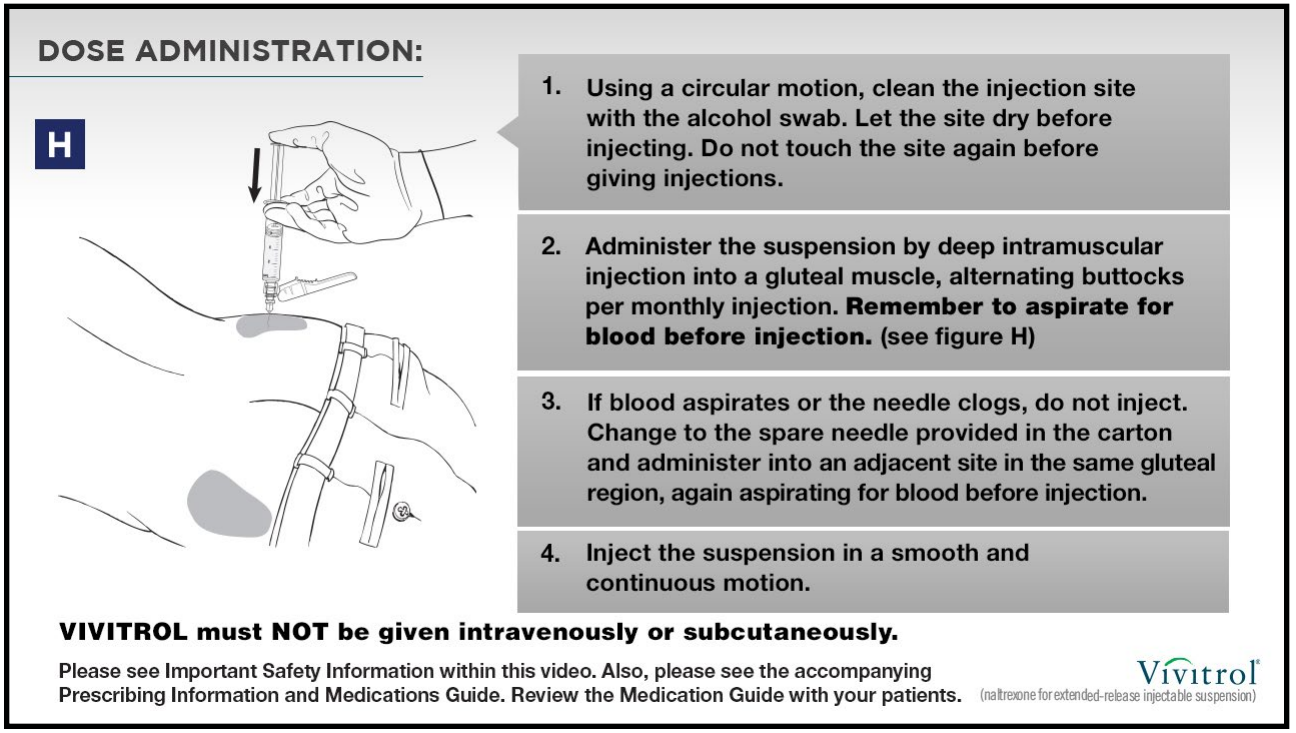
THE SUSPENSION IS NOW READY FOR IMMEDIATE ADMINISTRATION.



FRAME 21

VO:
DOSE ADMINISTRATION





FRAME 22

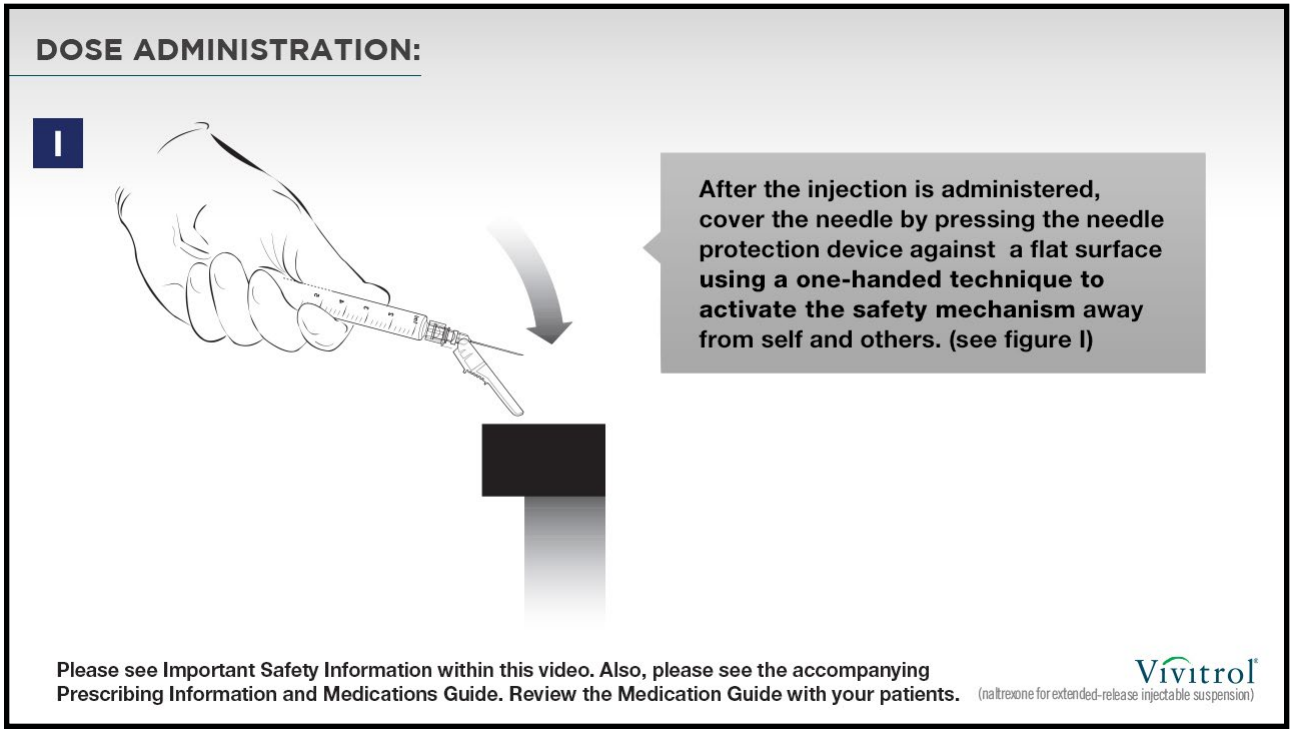
VO:
Using a circular motion, clean the injection site with the alcohol swab. Let the site dry before injecting. Do not touch the site again before giving injections.

Administer the suspension by deep intramuscular injection into a gluteal muscle, alternating buttocks per monthly injection. **Remember to aspirate for blood before injection.** (see figure H)

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.

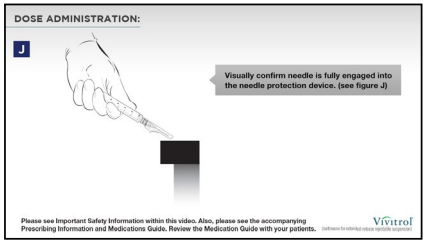
Inject the suspension in a smooth and continuous motion.

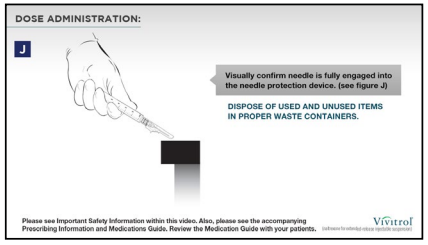
VIVITROL must NOT be given intravenously or subcutaneously.

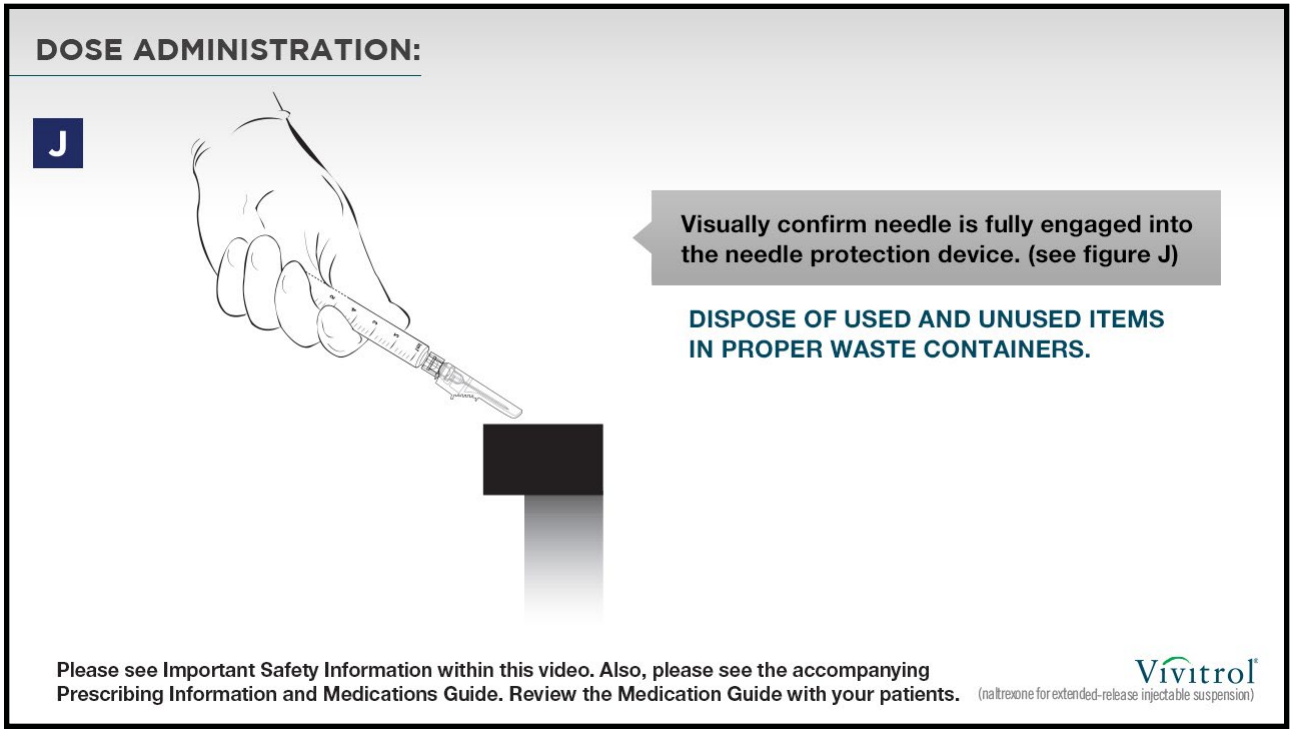


FRAME 23

VO:
After the injection is administered, cover the needle by pressing the needle protection device against a flat surface using a one-handed technique to activate the safety mechanism away from self and others. (see figure I)



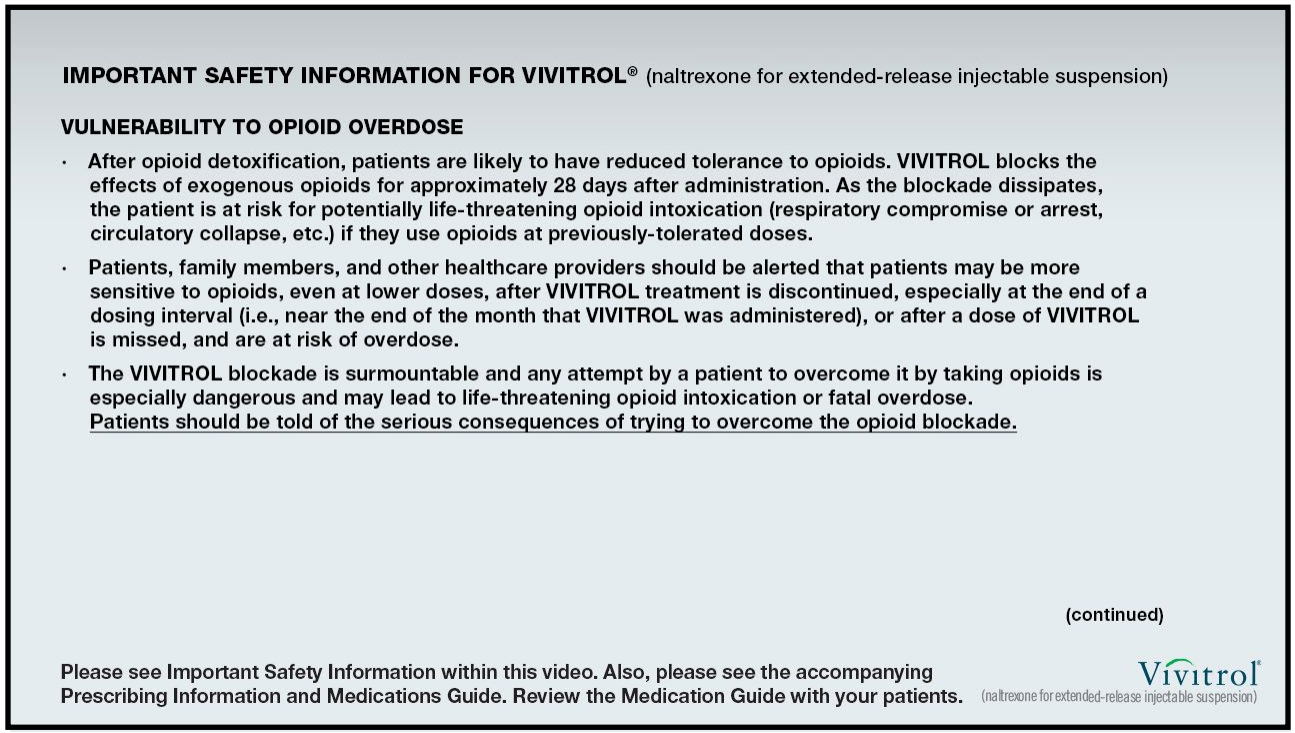




FRAME 24

VO:
Visually confirm needle is fully engaged into the needle protection device. (see figure J)

DISPOSE OF USED AND UNUSED ITEMS IN PROPER WASTE CONTAINERS.



FRAME 25

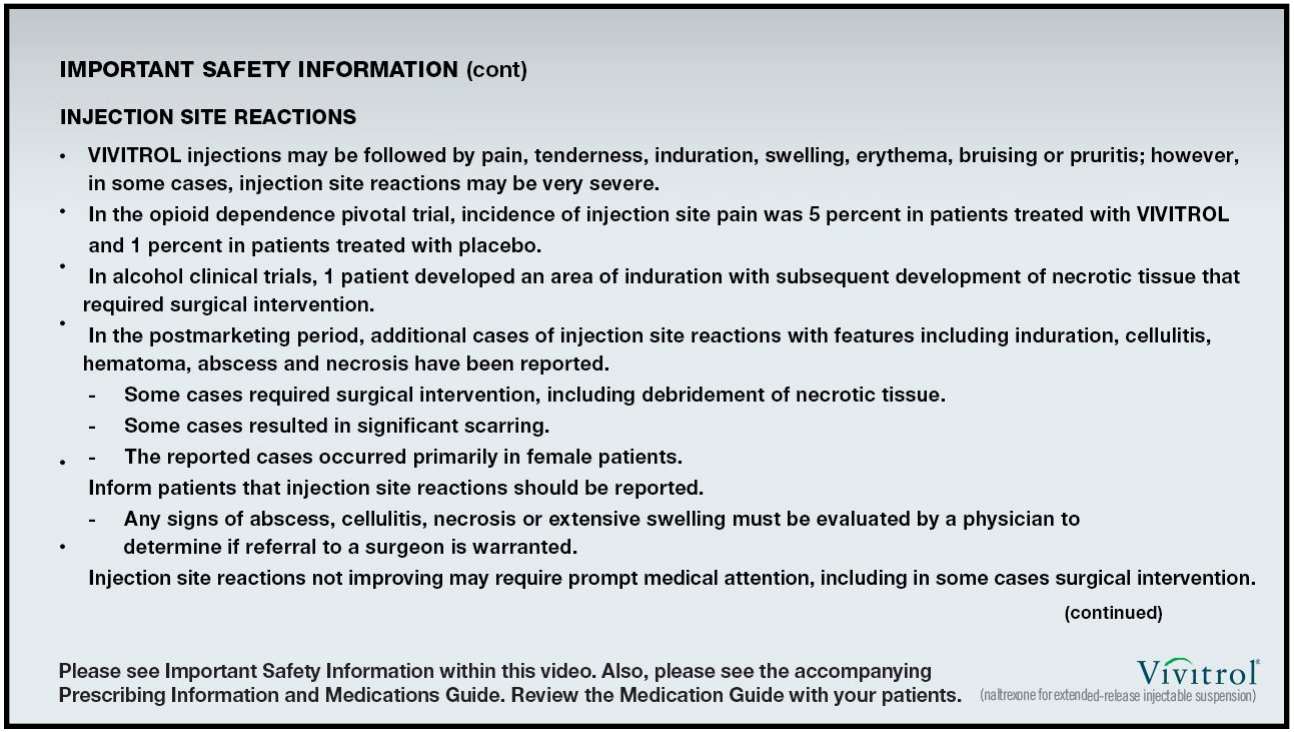
VO:
IMPORTANT SAFETY INFORMATION FOR VIVITROL® (naltrexone for extended-release injectable suspension)

VULNERABILITY TO OPIOID OVERDOSE

· After opioid detoxification, patients are likely to have reduced tolerance to opioids. VIVITROL blocks the effects of exogenous opioids for approximately 28 days after administration. As the blockade dissipates, the patient is at risk for potentially life-threatening opioid intoxication (respiratory compromise or arrest, circulatory collapse, etc.) if they use opioids at previously-tolerated doses.

· Patients, family members, and other healthcare providers should be alerted that patients may be more sensitive to opioids, even at lower doses, after VIVITROL treatment is discontinued, especially at the end of a dosing interval (i.e., near the end of the month that VIVITROL was administered), or after a dose of VIVITROL is missed, and are at risk of overdose.

· The VIVITROL blockade is surmountable and any attempt by a patient to overcome it by taking opioids is especially dangerous and may lead to life-threatening opioid intoxication or fatal overdose. Patients should be told of the serious consequences of trying to overcome the opioid blockade.



FRAME 26

VO:

IMPORTANT SAFETY INFORMATION (cont)

INJECTION SITE REACTIONS

· VIVITROL injections may be followed by pain, tenderness, induration, swelling, erythema, bruising or pruritis; however, in some cases, injection site reactions may be very severe.

· In the opioid dependence pivotal trial, incidence of injection site pain was 5 percent in patients treated with VIVITROL and 1 percent in patients treated with placebo.

· In alcohol clinical trials, 1 patient developed an area of induration with subsequent development of necrotic tissue that required surgical intervention.

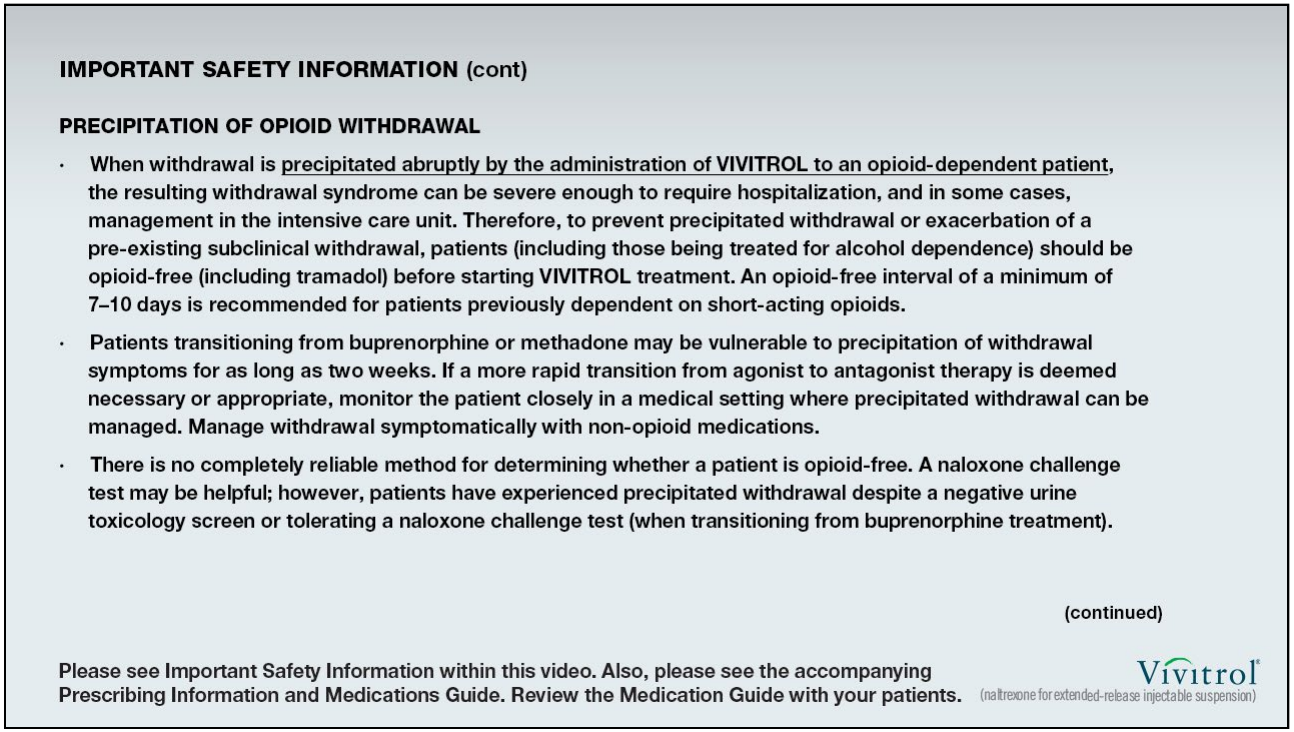
· In the postmarketing period, additional cases of injection site reactions with features including induration, cellulitis, hematoma, abscess and necrosis have been reported.

- Some cases required surgical intervention, including debridement of necrotic tissue.
- Some cases resulted in significant scarring.
- The reported cases occurred primarily in female patients.

· Inform patients that injection site reactions should be reported.

- Any signs of abscess, cellulitis, necrosis or extensive swelling must be evaluated by a physician to determine if referral to surgeon is warranted.

· Injection site reactions not improving may require prompt medical attention, including in some cases surgical intervention.

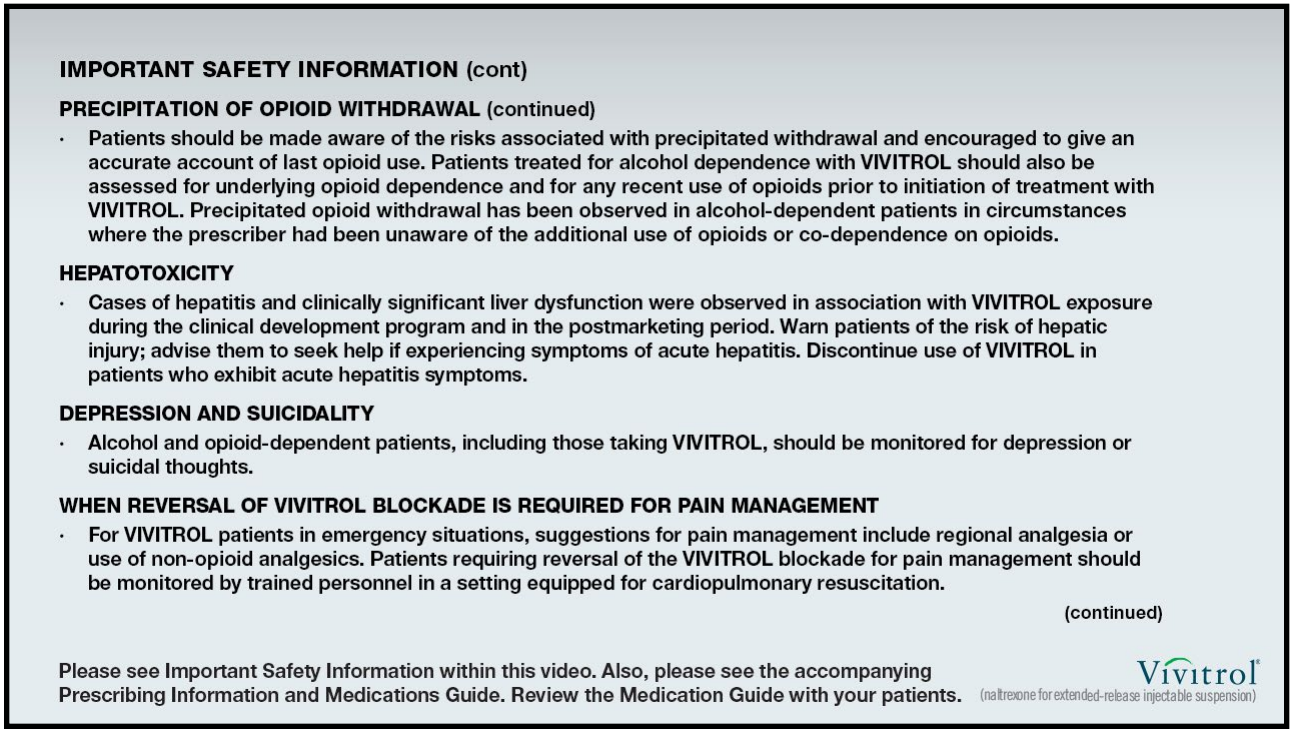


FRAME 27

VO:
IMPORTANT SAFETY INFORMATION (cont)

PRECIPITATION OF OPIOID WITHDRAWAL

- When withdrawal is precipitated abruptly by the administration of VIVITROL to an opioid-dependent patient, the resulting withdrawal syndrome can be severe enough to require hospitalization, and in some cases, management in the intensive care unit. Therefore, to prevent precipitated withdrawal or exacerbation of a pre-existing subclinical withdrawal, 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 precipitation of withdrawal symptoms for as long as two weeks. If a more rapid transition from agonist to antagonist therapy is deemed necessary or appropriate, monitor the patient closely in a medical setting where precipitated withdrawal can be managed. Manage withdrawal symptomatically with non-opioid medications.
- There is no completely reliable method for determining whether a patient is opioid-free. A naloxone challenge test may be helpful; however, patients have experienced precipitated withdrawal despite a negative urine toxicology screen or tolerating a naloxone challenge test (when transitioning from buprenorphine treatment).



FRAME 28

VO:

IMPORTANT SAFETY INFORMATION (cont)

PRECIPITATION OF OPIOID WITHDRAWAL (continued)

· Patients should be made aware of the risks associated with precipitated withdrawal and encouraged to give an accurate account of last opioid use. Patients treated for alcohol dependence with VIVITROL should also be assessed for underlying opioid dependence and for any recent use of opioids prior to initiation of treatment with VIVITROL. Precipitated opioid withdrawal has been observed in alcohol-dependent patients in circumstances where the prescriber had been unaware of the additional use of opioids or co-dependence on opioids.

HEPATOTOXICITY

· Cases of hepatitis and clinically significant liver dysfunction were observed in association with VIVITROL exposure during the clinical development program and in the postmarketing period. 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, including those taking VIVITROL, should be monitored for depression or suicidal thoughts.

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. Patients requiring reversal of the VIVITROL blockade for pain management should be monitored by trained personnel in a setting equipped for cardiopulmonary resuscitation.

IMPORTANT SAFETY INFORMATION (cont)

EOSINOPHILIC PNEUMONIA

- Consider the diagnosis of eosinophilic pneumonia if patients develop progressive dyspnea and hypoxemia.

HYPERSENSITIVITY REACTIONS

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

INTRAMUSCULAR INJECTIONS

- As with any intramuscular injection 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 EVENTS

- 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 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 also include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.

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

Vivitrol®
(naltrexone for extended-release injectable suspension)

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IMPORTANT SAFETY INFORMATION (cont)

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· The adverse events seen most frequently in association with VIVITROL in opioid-dependent patients also include hepatic enzyme abnormalities, injection site pain, nasopharyngitis, insomnia, and toothache.