Probuphine REMS Program Knowledge Assessment

PROBUPHINE® (buprenorphine) Implant CIII
Subdermal Use Only

To become certified in the Probuphine REMS Program as a Healthcare Provider Who Prescribes Probuphine or a Healthcare Provider Who Inserts Probuphine, you must answer all of the following questions correctly.

1. The goal of Probuphine REMS is to mitigate the risks of complications of migration, protrusion, expulsion and nerve damage associated with the insertion and removal of Probuphine and the risks of accidental overdose, misuse and abuse.
   a. True a. False

2. Which are the potential risks of insertion and removal of Probuphine?
   a. Migration
   b. Protrusion or expulsion
   c. Nerve damage
   d. All of the above

3. Which of the following statements is/are true?
   a. The certified Prescriber is responsible for ensuring that the healthcare provider inserting Probuphine has been certified.
   b. Patients on Probuphine must be monitored to ensure removal of Probuphine is performed by a certified HCP.
   c. Insertion procedures can only occur in the office in which a certified Prescriber is practicing.
   d. All of the above
   e. None of the above

4. Which of the following statements is/are **true**?
   a. Probuphine can be dispensed to patients for self-administration.
   b. Healthcare Providers Who Prescribe should use the patient counseling tool, ***What You Need to Know about Probuphine: A Patient's Guide*** to counsel patients about the risks and benefits of Probuphine therapy and give them a copy.
   c. The medication in Probuphine can be extracted and then abused in a manner similar to other opioids.
   d. B and C
   e. All of the above

5. Which of the following are important risk messages to convey to patients?
    a. There is no need to keep the implants (should they come out) away from children.
    b. Common risks associated with any minor surgical procedure (like the insertion of Probuphine implants) include itching, pain, irritation or redness, swelling, bleeding, bruising and scarring around the insertion site.
    c. It is impossible for the implant to come out by itself.
    d. Appropriate wound care is important to reduce the risk of complications associated with the insertion of Probuphine.
    e. B and D
    f. All of the above

6. When inserting the implants, the correct placement should be within the subdermal plane.
    a. True b. False

7. When inserting the applicator through the incision, the angle of the applicator should not exceed which of the following?
    a. 10 degree angle
    b. 20 degree angle
    c. 45 degree angle
    d. 90 degree angle

8. How far should the obturator be advanced to correctly position the implant?
    a. To the point where the plastic hub of the obturator locks with the plastic hub of the cannula.
    b. To the point where the stop line on the obturator is level with the blue bevel-up marking on the cannula.
    c. To the point where the stop line on the obturator is level with the distal marking on the cannula.
    d. None of the above

9. Which <u>one</u> of the following is <u>incorrect</u>?
    After inserting the first implant:
    a. Withdraw the locked applicator to the level of the distal marking seen in the incision opening.
    b. Withdraw the applicator completely from the incision and then re-insert it into the incision for the next implant.
    c. When redirecting the applicator, stabilize the previously inserted implant to avoid fracturing or mal-positioning the previously inserted implant
    d. Keep the bevel facing upward.

10. When inserting the implants, it is imperative to keep the bevel tip down throughout the procedure to ensure proper channel direction.
    a. True b. False

11. Once the individual implant has been advanced to the final position within the cannula, and you are ready to insert the next implant, what is the next step?
    a. Remove the entire applicator.
    b. Keep the obturator fixed in position and retract the cannula along the obturator.
    c. Force the implant into the tissues with the obturator.
    d. Take a coffee break.

12. On removal, one of the implants is extracted in 3 pieces. To ensure that you have removed the entire implant what should the cumulative length be of all 3 pieces when measured?
    a. 10 mm
    b. 18 mm
    c. 26 mm
    d. 50 mm

13. What should be done in the event that an implant cannot be palpated prior to removal?
    a. Reschedule the removal procedure. Order an ultrasound or MRI to locate the implant prior to removal.
    b. Reschedule the removal procedure. Order a CT to locate the implant prior to removal.
    c. Order an X-ray to locate the implant prior to removal.
    d. Perform the removal procedure and explore the site for the non-palpable implant.

14. What should be done for an implant that has come out of the skin?
    a. Ask the patient to dispose of the expelled implant.
    b. Tell the patient to try to push the implant back under the skin.
    c. Ask the patient to put the expelled implant in a plastic bag and bring it back to the office, then clean and close the expulsion site and insert a replacement implant in the same arm or contralateral arm.
    d. None of the above

15. Which of the following measures is/are recommended to prevent post-operative complications (e.g. wound infection, hematoma, protruding implants, etc.)?
    a. Advise the patient on proper care of the incision.
    b. Ensure the placement of the implants is at least 5mm from the incision opening.
    c. Apply a pressure bandage and cold compresses.
    d. a. and b. only
    e. a., b., and c.

Answer **True** or **False** for each of the statements associated with the following stem:
If an implant or implant fragment remains in the arm after a removal attempt, you should:

16. Request X-ray or CT imaging to locate the remaining implant or implant fragment(s).
    True _____ False____

17. Close the wound with sutures and have the patient return for imaging as soon as feasible followed by a second removal attempt on the day of localization.
    True____ False_____