PROBUPHINE® REMS Program

Healthcare Provider Who Preforms Probuphine Surgical Procedures[1] Enrollment Form

(for completion by healthcare providers who will only **insert/remove** Probuphine)

Probuphine is only available from healthcare providers who are certified in the Probuphine REMS Program to prescribe Probuphine. Probuphine may only be inserted or removed by healthcare providers who have successfully completed a live training program on the insertion and removal procedures and become certified to insert Probuphine implants. Patients must be monitored to ensure that Probuphine is removed by a healthcare provider certified to insert in the Probuphine REMS program.

Healthcare Providers Who Insert/Remove Agreement

By signing this form, I attest that:

1. I understand that Probuphine is only available to patients through healthcare providers who are certified by the Probuphine REMS Program.

2. I must comply with the program requirements to insert or remove Probuphine.

3. I have performed a surgical procedure in the three months immediately preceding enrollment in the REMS. This procedure was performed under local anesthesia, using aseptic technique, and included, at a minimum, making skin incision or placing sutures.

4. I have reviewed and understand the *Probuphine Prescribing Information*, the *Probuphine Instructions for Use*, and successfully completed the *Probuphine REMS Program Live Training: Lecture and Practicum* and the *Probuphine REMS Program Knowledge Assessment*; and meet the *Probuphine REMS Program Criteria for Procedural Competency.*

5. I understand the risks of migration, protrusion, expulsion, and nerve damage associated with insertion/removal of Probuphine and the risks of accidental overdose, misuse, and abuse associated with Probuphine.

[1] Patients having Probuphine removed must be monitored to ensure that removal is performed by a healthcare provider who is certified to insert. Healthcare providers certified to insert Probuphine are trained in removal procedures as well.

6. I understand the safe administration of Probuphine, including the proper insertion and removal techniques, as well as appropriate wound care.

7. I will provide each patient with a copy of the *Probuphine Medication Guide* prior to each insertion procedure and counsel each patient about:
    a. The risks associated with the insertion and removal of Probuphine.
    b. The risks of accidental overdose, misuse, and abuse, and if an implant comes out or protrudes from the skin.
    c. The importance of appropriate wound care.

8. I will document patient counseling in the *Probuphine REMS Program Insertion/Removal* Log or by using another method or system (e.g. electronic health record) specific to my medical practice.

9. I will perform the insertion and removal procedures in a healthcare setting in which a prescriber certified in the Probuphine REMS Program is also practicing.

10. I will assess the patient's need for removal of Probuphine.

11. I will ensure that this clinical setting has appropriate equipment to perform the insertion and removal procedures described in the *Probuphine Instructions for Use.*

12. I will maintain records of the insertion and removal of Probuphine including the date, serial number, number of implants inserted/removed, name of individual performing the procedure, and anatomical location of implants for individual patients on the *Probuphine REMS Program Insertion/Removal Log* or by using another method or system (e.g. electronic health record) specific to the prescriber's medical practice.

13. The removed implant contains a significant amount of residual buprenorphine. I will dispose of Probuphine implants in compliance with facility procedure for a Schedule lll drug product and per applicable local, state and federal regulations governing the disposal of pharmaceutical bio-hazardous waste.

14. I will not distribute, transfer, loan, or sell Probuphine outside the healthcare setting to anyone who is not certified as a prescriber in the Probuphine REMS Program.

15. I understand that I will need to recertify in the Probuphine REMS Program annually.

16. I understand that the Probuphine REMS Program may contact me via phone, mail, or email to survey me on REMS Program requirements.

17. I understand that I may request personnel from the Probuphine REMS program to provide training and support for my first Probuphine insertion and removal procedure.

18. I understand that personnel from the Probuphine REMS Program may contact me via phone, mail, or email to gather or to provide information related to the Probuphine REMS Program.

19. I will comply with requests to be audited by Titan Pharmaceuticals, or a third party, to ensure all processes and procedures are in place and are being followed for the Probuphine REMS Program, and appropriate documentation is available upon request.

20. I will report any adverse events associated with the insertion/removal of Probuphine and the risks of accidental overdose, misuse and abuse to Titan Pharmaceuticals at 1-844-859-6341.

Healthcare Provider Signature _____ Date _____

Print Name _____ **NPI #** _____

Please print the following information clearly and legibly in order to more easily process your enrollment in the Probuphine REMS Program.

First Name: _____

Last Name: _____

Practice or Healthcare Facility Name: _____

Practice or Healthcare Facility Street Address: _____

City: _____ State: _____ Zip: _____

Are you a: MD ☐ DO ☐ PA ☐ NP ☐ Other specify: _____

Clinical Specialty: Addiction Medicine ☐ Family Medicine ☐ Internal Medicine ☐ Psychiatry ☐ Other: _____

Telephone #:	Fax #:
E-mail:	Confirm E-mail:

Preferred Method of Communication (please select one): ☐ Fax ☐ Email

For more information, please contact the *Probuphine REMS Program* at 1-866-397-8939 or online at www.*ProbuphineREMS.com*.