# PROBUPHINE® REMS Program
# Healthcare Provider Dual[1] Enrollment Form

(for completion by healthcare providers who will **prescribe**, **insert**, and **remove** Probuphine)

Probuphine is only available from prescribers 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 Prescribe, Insert, and 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 prescribe, insert, and remove Probuphine.

3. I have performed a surgical procedure in the last three months. This procedure was performed under local anesthesia, using aseptic technique, and included, at a minimum, making skin incisions 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*, 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.

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

[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.

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

8. I will document patient counseling on 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 order Probuphine only from an authorized wholesaler/distributor.

10. I will not transfer Probuphine outside the healthcare setting to anyone who is not certified as a Healthcare Provider Who Prescribes in the Probuphine REMS Program.

11. I will perform the insertion and removal procedures in a healthcare setting with appropriate equipment to perform the insertion and removal procedures as described in the *Probuphine Instructions for Use.*

12. I will document the insertion and removal of Probuphine including the date, serial number, number of implants inserted/removed, name of individual performing the procedure, and 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 my medical practice; and I will maintain such documentation of insertion and removal of Probuphine in each patient's medical record.

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 III drug product and per applicable local, state and federal regulations governing the disposal of pharmaceutical bio-hazardous waste.

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

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

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

17. I understand 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.

18. I will comply with requests to be audited by Braeburn Pharmaceuticals to ensure all recertification requirements are being followed for the Probuphine REMS Program, and appropriate documentation is available upon request.

19. I will report any adverse events associated with the insertion/removal of Probuphine and the risks of accidental overdose, misuse and abuse to Braeburn 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 ☐

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 *ProbuphineREMS.com*.**