

PROBUPHINE® REMS Program

Healthcare Provider Who Inserts/Removes Enrollment Form

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

Probuphine is only available from healthcare providers who are certified in the *Probuphine REMS Program* to prescribe Probuphine and may only be inserted or removed by healthcare providers who are certified in the *Probuphine REMS Program* to insert or remove Probuphine.

To become certified in the *Probuphine REMS Program* as a healthcare provider who inserts/removes Probuphine, you must:

1. Successfully complete the *Probuphine REMS* training requirements which include:
 - a. *Probuphine REMS Program Didactic Training*
 - b. *Probuphine REMS Program Knowledge Assessment*
 - c. *Probuphine REMS Program Live Practicum Training*
 - d. *Probuphine REMS Program Criteria for Procedural Competency*
2. Complete and submit the *Probuphine REMS Program Healthcare Provider Who Inserts/Removes Enrollment Form*

Attestations for Healthcare Providers Who Insert/Remove

By signing this form, I attest that:

1. I understand that Probuphine is only available through healthcare providers who are certified by the *Probuphine REMS Program* and that I must comply with the program requirements to insert or remove Probuphine.
2. I have reviewed and understand the *Probuphine Prescribing Information*, the *Probuphine Instructions for Use*, and successfully completed the *Probuphine REMS Program Live Didactic and Practicum Training* and the *Probuphine REMS Program Knowledge Assessment*; and meet the *Probuphine REMS Program Criteria for Procedural Competency*.
3. I understand the risks of migration, protrusion, expulsion, and nerve damage associated with improper insertion/removal of Probuphine and the risks of accidental overdose, misuse, and abuse associated with Probuphine.
4. I understand appropriate patient selection for the safe administration of Probuphine, including the proper insertion and removal techniques, as well as appropriate wound care.
5. 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 increased risks associated with the improper insertion and removal of Probuphine,
 - b. The risks of accidental overdose, misuse and abuse, and
 - c. Appropriate wound care.
6. 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.
7. I will insert and remove Probuphine under the supervision of a healthcare provider who is certified in the *Probuphine REMS Program* to prescribe Probuphine.
8. I will perform the insertion and removal procedures in a clinical setting in which a REMS certified Healthcare Provider Who Prescribes Probuphine practices. This clinical setting must have

appropriate equipment to perform the insertion and removal procedures described in the *Probuphine Instructions for Use*.

9. I will document the insertion and removal of Probuphine including the date, number of rods inserted/removed, name of individual performing the procedure, and location of rods 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.
10. I will dispose of Probuphine implants in keeping with local, state and federal regulations governing the disposal of pharmaceutical bio-hazardous waste.
11. I will not transfer Probuphine to anyone not certified in the *Probuphine REMS Program*.
12. I understand that the *Probuphine REMS Program* may contact me via phone, mail, or email to survey me on the effectiveness of the REMS Program requirements.
13. I understand that I may request personnel from the *Probuphine REMS* to observe my first Probuphine insertion and removal.
14. I agree personnel from the *Probuphine REMS Program* may contact me to gather information or resolve discrepancies or to provide other information related to the Probuphine REMS Program.
15. I will report any adverse events associated with the improper insertion/removal of Probuphine and the risks of accidental overdose, misuse and abuse to Braeburn Pharmaceuticals at 1-844-859-6341.

Healthcare Provider Who Inserts/Removes Signature

Date

Print Name

NPI #

First Name:

Last Name:

Practice Name:

Street Address:

City:

State:

Zip:

Are you a: MD DO PA NP Other: _____

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 1-844-859-6341 or on line at *ProbuphineREMS.com*.