

Probuphine® REMS Program

Healthcare Provider Who Inserts/Removes Recertification Form

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

Probuphine is only available from healthcare providers who are certified in the *Probuphine REMS Program* to prescribe Probuphine. In addition, Probuphine may only be inserted or removed by healthcare providers who are certified in the *Probuphine REMS Program* to perform these procedures.

Ongoing recertification is required to maintain your certification to insert or remove Probuphine. These requirements are outlined below:

Healthcare Professional Background	Recertification Requirements ¹
Has current operating privileges at hospitals or out-patient surgical centers	Review the <i>Probuphine Insertion, Removal and Complications Instructional Video</i> found on the Probuphine REMS website every 2 years
Has <u>no</u> operating privileges at hospitals or out-patient surgical centers and <u>in the past 12 months</u> has:	
Performed 5 or more successful* implantations and removals	Review <i>Probuphine Insertion, Removal and Complications Instructional Video</i> every year
Performed less than 5 successful* implantations and removals	Attend live training

¹ Denotes the minimal requirements. Healthcare Professionals should utilize the tools provided for recertification as needed to ensure proper insertion and removal of Probuphine is conducted in accordance with the *Probuphine REMS Program*.

To maintain your certification to insert or remove Probuphine, you must attest that you have completed the following requirements:

Recertification Attestations for Healthcare Providers Who Insert/Remove

By signing this form, I attest that:

I meet one of the following recertification requirements (please select):

- I am an HCP with operating privileges at hospitals or out-patient surgical centers and I have reviewed the *Probuphine Insertion, Removal and Complications Instructional Video* within 2 years of my last *Probuphine REMS* certification.
- I am an HCP with no operating privileges at hospitals or out-patient surgical centers. I have performed 5 or more successful* implantations and removals during the past 12 months and I have reviewed the *Probuphine Insertion, Removal and Complications Instructional Video*.

- I am an HCP with no operating privileges at hospitals or out-patient surgical centers. I have performed less than 5 successful* implantations and removals during the past 12 months and successfully completed the *Probuphine REMS Program Live Didactic and Practicum*.

I further attest to the following:

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*.
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 personnel managing the *Probuphine REMS Program* may contact me via phone, mail, or email to gather information, resolve discrepancies or to provide other information related to the *Probuphine REMS Program*.
13. 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.

* "Successful" implantation and removal procedures exclude attempted procedures that require assistance of other surgical specialties for completion. Removal procedures assisted by imaging studies prior to completion can be included, provided that the HCP successfully removes all implants identified by imaging without involving additional surgical consultants.

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