

## **PROBUPHINE<sup>®</sup> REMS Program**

### **Healthcare Provider Who Prescribes Enrollment Form**

(for completion by healthcare providers who will only prescribe 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 Prescribe Agreement**

By signing this form, I attest that:

1. I understand that Probuphine is only available to patients through healthcare providers who are certified in the Probuphine REMS Program and that I must comply with the program requirements to prescribe Probuphine.
2. 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*.
3. 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.
4. I will provide each patient 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, if an implant comes out or protrudes from the skin.
  - c. The importance of appropriate wound care
5. I will order Probuphine only from an authorized wholesaler/distributor.
6. 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.
7. I understand that Probuphine may only be inserted by healthcare providers who are certified in the Probuphine REMS Program specifically to insert Probuphine.

8. I understand that patients having Probuphine removed must be monitored to ensure the removal is performed by a healthcare provider who is certified to insert and is trained on the proper removal procedure for Probuphine.
9. I will make arrangements for a healthcare provider who is certified in the Probuphine REMS Program to insert Probuphine to perform the insertion and removal procedures in the healthcare setting in which I am practicing.
10. I will ensure that the Healthcare Provider Who Inserts/Removes Probuphine in the healthcare setting in which I am practicing documents 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 the healthcare provider's practice; and I will maintain such documentation of insertion and removal of Probuphine in each patient's medical record.
11. I understand that the Probuphine REMS Program may contact me via phone, mail, or email to survey me on the REMS Program requirements.
12. 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.
13. 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.

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Prescriber's Signature

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Date

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**Print Name**

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**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 #:
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E-mail:	Confirm E-mail:
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Preferred Method of Communication (please select one):  Fax  Email

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