

PROBUPHINE REMS Program
Pharmacy Enrollment Form

Instructions

Probuphine® (buprenorphine) implant is only available through the Probuphine Risk Evaluation and Mitigation Strategy (REMS) Program. Before Probuphine is provided, pharmacies must:

1. Designate an authorized representative.
2. Complete and sign this **Probuphine REMS Program Pharmacy Enrollment Form** and submit it to the REMS Program.
3. Agree to train all relevant staff involved in dispensing that Probuphine is only dispensed in healthcare settings in which a certified prescriber is practicing.
4. Agree to verify that Probuphine is dispensed directly to healthcare settings in which a certified prescriber is practicing. **Probuphine must not be dispensed directly to a patient.**

The **Probuphine REMS Program Pharmacy Enrollment Form** contains two sections:

- “Authorized Representative Information and Responsibilities” section – page 2
- “Dispensing Pharmacy Information” section – page 3

The authorized representative will ensure that each dispensing pharmacy location meets the REMS requirements for permission to order and dispense Probuphine. For the initial enrollment, both sections of the **Probuphine REMS Program Pharmacy Enrollment Form** must be submitted for each dispensing pharmacy location. To add additional dispensing pharmacy locations after the initial enrollment, you may complete just the “Dispensing Pharmacy Information” section. The certification will be confirmed by the REMS Program prior to shipping Probuphine.

If a designated authorized representative changes, the new authorized representative must complete and sign a new **Probuphine REMS Program Pharmacy Enrollment Form**, including a “Dispensing Pharmacy Information” section for each location.

Enrollment can be done online, by fax, email, or mail.

- To enroll **online**, please go to www.PROBUPHINEREMS.com.
- For enrollment via **FAX**, please complete all required fields on the form and fax the section(s) to 609-423-0965.
- For enrollment via **e-mail**, please complete all required fields on the form and email the section(s) to info@reacxpharma.com.
- For enrollment via **mail** please complete all required fields on the form and mail the section(s) to PROBUPHINE REMS Program, 400 Oyster Point Blvd. Suite 505, South San Francisco, CA 94080.

Probuphine is only available to certified pharmacies. For questions about the Probuphine REMS Program or how to enroll, visit www.PROBUPHINEREMS.com or contact the Probuphine REMS Program at 1-833-824-0824

**PROBUPHINE REMS Program
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Authorized Representative Information and Responsibilities

AUTHORIZED REPRESENTATIVE INFORMATION

Role

<input type="checkbox"/> Pharmacist	<input type="checkbox"/> Other _____
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Contact details

First name:	Last name:	Middle initial:
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Pharmacy Name:

Address:

City:	State:	Zip:
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Telephone number:	Alternate telephone number:	Office fax:
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Email:	Preferred method of communication:
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I am the authorized representative designated by my pharmacy to carry out the certification process and oversee implementation of and compliance with the REMS. By signing this form, I agree, on behalf of myself and my pharmacy, with the REMS requirements. As a condition of certification, I agree to:

- Complete and sign the **Probuphine REMS Program Pharmacy Enrollment Form** and submit it to the REMS.
- Train all relevant staff involved in dispensing that Probuphine is only dispensed in healthcare settings in which a certified prescriber is practicing and is not dispensed directly to the patient.
- Establish processes and procedures to verify that Probuphine is provided to a healthcare setting in which a certified prescriber is practicing, and the drug is not dispensed directly to the patient.
- Verify that the healthcare provider who will receive the drug is certified to prescribe Probuphine.
- Have a new authorized representative enroll in the REMS by completing **Probuphine REMS Program Pharmacy Enrollment Form** if the authorized representative changes.
- Not distribute, transfer, or sell Probuphine, except to healthcare settings in which a certified prescriber is practicing.
- Maintain records of staff training and of all processes and procedures including compliance with those processes and procedures.
- Maintain records of all shipments of Probuphine and submit to Fedson Inc.
- Comply with audits carried out by Fedson Inc. or a third party acting on behalf of Fedson Inc. to ensure that all processes and procedures are in place and are being followed.

I understand that this enrollment applies to my pharmacy for which I am the designated authorized representative.

Pharmacy Authorized Representative Signature:	Date: (MM/DD/YYYY)
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Dispensing Pharmacy Information			
Pharmacy Name:			
Street Address:			
City:	State:	Zip:	
Facility identifiers (provide at least 1)	NPI:	NCPDP:	DEA:
Authorized Representative Name:			
Dispensing Pharmacy Point of Contact Name:			
Telephone number:	Alternate telephone number:	Office fax:	
Email:	Preferred method of communication:		
I am the designated authorized representative for this pharmacy location			
Pharmacy Authorized Representative Signature:		Date: (MM/DD/YYYY)	