

What is XIAFLEX

XIAFLEX is approved for the treatment of adult men with Peyronie's disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. XIAFLEX should be administered by a healthcare provider experienced in the treatment of male urological diseases, who has completed required training for use of XIAFLEX in the treatment of Peyronie's disease.

What is the XIAFLEX REMS

A REMS (*Risk Evaluation and Mitigation Strategy*) is a strategy to manage known or potential serious risks associated with a drug and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. Endo Pharmaceuticals has worked with the FDA to develop the XIAFLEX REMS Program.

The XIAFLEX REMS requires a review of educational materials, training, and certification.

XIAFLEX is available for the treatment of Peyronie's disease only through the XIAFLEX REMS Program. The XIAFLEX REMS Program requirements include:

- **Training** for healthcare providers on the risks of corporal rupture and other serious injuries to the penis, and how to properly administer XIAFLEX.
- **Certification** in the XIAFLEX REMS Program by completing training and enrollment in the program.
- **Patient Counseling** about the risks of corporal rupture and other serious injuries to the penis and the importance of patient adherence to post-injection instructions. Healthcare Providers must give patients the Patient Counseling Tool, "*What You Need to Know About XIAFLEX Treatment for Peyronie's Disease: A Patient Guide*", after each XIAFLEX injection.
- **Restricted Distribution** through specially certified healthcare settings (e.g., pharmacies, practitioners, hospitals or outpatient settings).

Healthcare Provider Certification

To become certified in the XIAFLEX REMS Program, healthcare providers must read the prescribing information, take the training (video or guide) and complete the Enrollment Form.

Pharmacy/Healthcare Setting Certification

To become certified in the XIAFLEX REMS Program, pharmacies and healthcare settings must complete the Pharmacy/Healthcare Setting Enrollment Form.

For more information about the XIAFLEX REMS Program, call 1-877-313-1235.

If you have product-related questions or to report adverse events, please contact the XIAFLEX Medical Information Call Center at 1-800-462-3636. Adverse events may also be reported to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Materials for Healthcare Providers

- [Healthcare Provider Enrollment Form for Peyronie's Disease](#)
- [Training Guide for the Administration of XIAFLEX for Peyronie's Disease](#)
- [Training Video for the Administration of XIAFLEX for Peyronie's Disease](#)
- [What You Need to Know About XIAFLEX Treatment for Peyronie's Disease: A Patient Guide \(a patient counseling tool\)](#)
- [Prescribing Information](#)
- [Medication Guide](#)

Materials for Healthcare Facilities

- [Healthcare Facility Enrollment Form for Peyronie's Disease](#)

Materials for Patients

- [What You Need to Know about XIAFLEX Treatment for Peyronie's Disease: A Patient Guide](#)
- [Medication Guide](#)

Resources

- [Certified Healthcare Setting and Healthcare Provider Lookup](#)

XIAFLEX REMS Program Certification Lookup

To use the Program Certification Lookup, please start by choosing a tab; either Prescribing Healthcare Provider or Healthcare Setting. If searching for a Prescribing Healthcare Provider, please enter the Zip Code or Certification ID or NPI Number or Last Name and State and press the **Search** button. If searching for a Healthcare Setting, please enter the Certification ID or the Zip Code or City and State and press the **Search** button. Search results include contact information and certified participants/locations in the XIAFLEX REMS Program.

Prescribing Healthcare Provider
Healthcare Setting

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Show entries

| Certification ID | Name | Address | City | State | Zip | Phone |
|------------------|------------|----------------------------|-----------|----------|-------|--------------|
| 3112345 | JOHN MULYE | 900 East Valley street 123 | Baltimore | Maryland | 03909 | 480-909-7890 |

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Prescribing Healthcare Provider Healthcare Setting

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| Certification ID <input type="text"/> | Zip Code <input type="text"/> | City <input type="text" value="BALTIMORE"/> | State <input type="text" value="MD"/> | <input type="button" value="Search"/> |
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| Certification ID | Name | Address | City | State | Zip | Phone |
|------------------|--------------|----------------------------|-----------|----------|-------|--------------|
| 2112345 | ABC Pharmacy | 900 East Valley street 123 | Baltimore | Maryland | 03909 | 480-123-4567 |

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