A REMS 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. Auxilium has worked with the FDA to develop materials to communicate to healthcare providers and patients, the potential serious risks associated with use of XIAFLEX.

**XIAFLEX** is approved for two indications:

- the treatment of adult patients with Dupuytren's contracture with a palpable cord
- 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

Each indication has separate REMS requirements and educational materials. Follow the links below to learn more about the XIAFLEX REMS for each indication.

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RMX-00004  
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A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug and is required by the Food and Drug Administration to ensure that the benefits of the drug outweigh its risks. In order for Auxilium to communicate certain risks to ensure that XIAFLEX is injected properly, Auxilium has worked with the FDA to develop materials to communicate the risks of tendon rupture and hypersensitivity reactions. The REMS program is designed to inform health care providers about the potential risks with XIAFLEX. To learn more about serious risks of XIAFLEX, read the Full Prescribing Information, including the Medication Guide, and important safety information by clicking above, and discuss it with your patients.

The goals of the XIAFLEX REMS for Dupuytren’s contracture are:

- To mitigate the risks of tendon rupture and serious adverse reactions affecting the injected extremity associated with the use of XIAFLEX by informing healthcare providers about how to properly inject XIAFLEX and perform finger extension procedures.

- To inform healthcare providers about the potential risk of serious hypersensitivity reactions (including the potential for anaphylaxis) associated with XIAFLEX treatment.
To access training materials on how to properly administer XIAFLEX for Dupuytren’s contracture click here:

- **Procedure Training Video**
- **Training Guide for the Administration of XIAFLEX (pdf)**

Please see the [Dear Healthcare Provider Letter](#) for more information about XIAFLEX for Dupuytren’s contracture.

XIAFLEX for the treatment of Dupuytren’s contracture is available only through a managed distribution program. The XIAFLEX managed distribution program requires Healthcare Providers and Healthcare Settings that intend to use XIAFLEX for treatment of Dupuytren’s contracture to complete an enrollment process. To enroll as a Healthcare Provider and/or a Healthcare Setting click the link below:

[XIAFLEX Enrollment for Dupuytren’s Contracture](#)
XIAFLEX REMS for Peyronie's Disease

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. Auxilium has worked with the FDA to develop the XIAFLEX REMS Program.

XIAFLEX REMS Program Overview

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 below (video or guide) and complete the Enrollment Form.

- Prescribing Information
- Training Video for the Administration of XIAFLEX for Peyronie’s Disease
- Training Guide for the Administration of XIAFLEX for Peyronie’s Disease (pdf)
- Patient Counseling Tool, “What You Need to Know About XIAFLEX Treatment for Peyronie’s Disease: A Patient Guide”
- Healthcare Provider Enrollment Form for Peyronie's Disease

Pharmacy/Healthcare Setting Certification

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

- Pharmacy/Healthcare Setting Enrollment Form for Peyronie's Disease

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For information on XIAFLEX treatment for Dupuytren's contracture please click on this link:

- XIAFLEX REMS for Dupuytren’s contracture