

ZULRESSO™ REMS Program Overview for Pharmacies

This Program Overview specifically applies to Pharmacies that dispense ZULRESSO that are not within the same institution as the certified Healthcare Setting.

What is the ZULRESSO REMS (Risk Evaluation and Mitigation Strategy)?

A REMS is a strategy to manage known or potential risks associated with a drug and is required by the U.S. Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. ZULRESSO is available only through a restricted distribution program called the ZULRESSO REMS because of the **risk of serious harm resulting from excessive sedation and sudden loss of consciousness during the ZULRESSO infusion.**

ZULRESSO is intended for infusion only in a certified Healthcare Setting.

What are the ZULRESSO REMS requirements?

- Only administer ZULRESSO to patients in a medically supervised setting that provides monitoring during administration.
- Only certified Pharmacies and Healthcare Settings can dispense ZULRESSO.
- Educate patients on the risks of serious harm from excessive sedation and sudden loss of consciousness and the need for monitoring while ZULRESSO is administered.
- Enroll all patients in a registry.

How can a Pharmacy become enrolled in the ZULRESSO REMS?

In order to become enrolled, the Pharmacy must:

1. Designate an Authorized Representative to carry out the certification process and oversee implementation and compliance with the ZULRESSO REMS on behalf of the Pharmacy, including:
 - Training all staff involved in dispensing that ZULRESSO must only be dispensed to a certified Healthcare Setting
 - Establishing processes and procedures to verify, prior to dispensing ZULRESSO, that the Healthcare Setting is certified in the ZULRESSO REMS
2. Have the Authorized Representative review this **Program Overview**.
3. Complete the **Pharmacy Enrollment Form** and submit it to the ZULRESSO REMS.
4. Verify, **prior to dispensing ZULRESSO**, that the Healthcare Setting is certified in the ZULRESSO REMS by calling the ZULRESSO REMS Coordinating Center at 844-472-4379.

Visit www.zulressorems.com to begin enrollment and for additional information.

You may also contact the ZULRESSO REMS at 844-472-4379.



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