

- Starting October 12, 2015, ALL clozapine products are only available through the Clozapine REMS Program
- There are important changes to neutropenia monitoring recommendations and treatment algorithm for clozapine

Dear Prescriber:

The FDA has required this safety notice to inform healthcare providers about:

1. The new Risk Evaluation and Mitigation Strategy (REMS) Program for all clozapine products
2. Changes to neutropenia monitoring requirements and treatment algorithm for clozapine

What is the shared Clozapine REMS Program?

The Clozapine REMS Program replaces all individual clozapine registries. It includes all clozapine products under one shared program to minimize the risk of neutropenia and provides a new, **centralized point** of access:

- For **prescribers and pharmacists** to receive training, complete the knowledge assessment, and certify for access to all clozapine products
- To **enroll and manage patients** on clozapine treatment

What are the key changes to neutropenia monitoring recommendations and treatment algorithm for clozapine?

- Absolute neutrophil count (ANC) is the only test result accepted in the shared Clozapine REMS Program to monitor for neutropenia
- Patients with Benign Ethnic Neutropenia (BEN) can be treated with clozapine and have a separate ANC monitoring algorithm
- ANC thresholds to start and continue clozapine treatment are lower
- Prescribers have greater flexibility to make patient-specific decisions about continuing and resuming treatment in patients who experience moderate and/or severe neutropenia

Please review ***What's New with Clozapine*** for additional information about changes related to clozapine treatment and monitoring.

CLOZAPINE REMS

The Single Shared System for Clozapine
No Blood, No Drug™

What do I need to do?

Starting October 12, 2015, you must certify in the Clozapine REMS Program. You can no longer enroll or manage patients through the individual clozapine patient registries.

Prescribers have additional time to certify, if:

- you have a patient who has an ANC or white blood cell (WBC) count reported to one or more of the individual clozapine patient registries in the previous 3 years, or
- you have a patient who was on the National Non-Rechallenge Master File (NNRMF)

Starting October 12, 2015 - To certify you must:

1. Review *Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*
2. Successfully pass the Knowledge Assessment
3. Complete and submit the one-time *Clozapine REMS Prescriber Enrollment Form*

To assist you with the Clozapine REMS Program requirements, once you are certified, you may appoint designee(s) to enroll patients and enter ANC results on your behalf. However, designees must also certify in the Clozapine REMS Program. All program materials are available at www.clozapinerems.com.

Prescribers and designees can be certified through the Clozapine REMS Program at www.clozapinerems.com, by fax 844-404-8876, or by calling the Clozapine REMS Program at 844-267-8678 for more information.

Sincerely,

The Clozapine REMS Program

Please review ***Clozapine and the Risk of Neutropenia: A Guide for Healthcare Providers*** available at www.clozapinerems.com for more detailed information about the Clozapine REMS Program requirements, and additional information about changes related to clozapine treatment and monitoring.

This letter does not contain the complete safety profile for clozapine.

Visit www.clozapinerems.com to review the complete Prescribing Information.

The products covered under the Clozapine REMS Program are: Clozaril® (clozapine) tablets, for oral use • Versacloz® (clozapine, USP) oral suspension • Fazaclo® (clozapine USP) orally disintegrating tablets • Approved generic equivalents of these products