



Frequently Asked Questions



Q: With the Clozapine REMS Program, how difficult is it to change suppliers?

A: It is much easier now because the Clozapine REMS program is a shared program that includes all manufacturers of Clozapine. A change in Clozapine suppliers should not require additional work, and the process for submission to the Clozapine REMS is the same no matter which supplier of Clozapine oral tablets is dispensed.

Q: A local prescriber is concerned about changing suppliers of Clozapine. What assurances can I provide?

A: Mayne Pharma Clozapine tablets, USP are FDA approved and listed in the Orange Book with an AB rating. They undergo the same rigorous process that all drugs go through in order to be approved by the FDA. Many states directly reference or use the Orange Book as a reference for generic substitution guidance. Please check your state pharmacy laws.

Generic pharmaceutical manufacturers must prove to the FDA that their version of a drug:

- contains the same active ingredient;
- is identical in strength, dosage form, and route of administration;
- has the same indications, dosing, and labeling;
- provides the same expected efficacy and safety profile to patients ("bioequivalent")

Generic medicines must be safe and effective to be approved by the FDA. The FDA also requires generic drug manufacturers to:

- meet the same batch-to-batch requirements for strength, purity, and quality as the original manufacturer; and
- follow the same strict "Good Manufacturing Practices" rules.

Q: As Clozapine strengths are changed by the prescriber, I have patients who are concerned about the Clozapine tablet appearance. How can Mayne help with this inquiry?

A: All Mayne Clozapine tablets, USP are available in pale yellow tablets of 25 mg, 50mg, 100 mg, and 200mg for oral administration. Mayne Clozapine tablets, USP are round, flat face, bevel edge, pale-yellow, tablets with a score on one side.

Q: I prefer to buy American products whenever possible at my pharmacy. Is Mayne a foreign manufacturer?

A: Mayne Pharma is headquartered in Australia with US manufacturing in Greenville, NC. Mayne Clozapine tablets USP are made in the USA via a manufacturing partnership.

Q: How does a healthcare provider report an adverse event, product complaint, or obtain medical information about Clozapine?

A: Promptly report suspected adverse events associated with the use of a Clozapine directly to the Clozapine REMS Program Contact Center at 844-267-8678. You should also report adverse event information to the FDA MedWatch Reporting System by telephone at (800) FDA-1088, by mail using Form 3500, or online. Downloadable reporting forms and online reporting forms are available at [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](#)

To report a product complaint or if you require medical information, you may also contact the Clozapine REMS Program Contact Center using the number provided above.

If you have any questions call the Clozapine REMS Program Contact Center at 844-267-8678 for assistance.

REFERENCES

[What is the Clozapine REMS Program?](#)

Clozapine is associated with severe neutropenia (absolute neutrophil count (ANC) less than 500/ μ L). The requirements to prescribe, dispense, and receive Clozapine are incorporated into a single, shared program called the Clozapine Risk Evaluation and Mitigation Strategy (REMS). A REMS is a strategy to manage known or potential risks associated with a drug or group of drugs, and is required by the FDA for Clozapine to ensure that the benefits of the drug outweigh the risk of severe neutropenia. The Clozapine REMS Program replaces the individual Clozapine patient registries and the National Non-Rechallenge Master File (NNRMF).

<https://www.Clozapinerems.com/CpmgClozapineUI/home.u>

[Generic Drugs- What is a generic medicine? Are generic drugs safe?](#)

<https://www.accessiblemeds.org/generic-medicines>

For additional information go to www.clozapinerems.com or call 844-267-8678.

Also visit our Clozapine webpage at www.maynepharma.com/clozapine