

Clozapine REMS Discontinuation Information

What You Need to Know After the End of the REMS Program (Effective February 24, 2025)

Clozapine Availability

Clozapine is still available through pharmacies. If your pharmacist is unsure, inform them the REMS program was officially discontinued by the FDA on February 24, 2025.

Pharmacy Requirements

Pharmacies are no longer required to check the REMS system before dispensing clozapine. Some may still ask for lab results, but this is based on individual pharmacy policy-not federal requirement.

Prescription Fills

Clozapine prescriptions should now be treated like any other medication. They can be written for 30-day or 90-day supplies. Refills are no longer dependent on lab results being entered into a REMS system. Your pharmacy does not need to verify labs in order to dispense your medication. Follow your doctor's lab schedule, but lab reporting is now managed between you and your provider.

ANC Monitoring

ANC (Absolute Neutrophil Count) monitoring is still recommended and important, but your doctor now decides the schedule. Monitoring should continue based on your provider's clinical judgment.

What Is a Normal ANC?

An ANC above 1500/ μ L is considered normal for most patients.

Benign Ethnic Neutropenia (BEN)

Some individuals-especially those of African, Middle Eastern, or Caribbean descent-may have naturally lower ANC levels without increased infection risk. For these patients, an ANC above 1000/ μ L is usually acceptable.

Highest Risk Period

The risk of dangerous drops in white blood cell count (severe neutropenia) is highest during the first 18 weeks of treatment. After that, the risk decreases.

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Recommended Monitoring (per manufacturer)

The Clozaril manufacturer recommends the following before starting treatment:

- Confirm ANC >1500/ μ L for most patients.
- For patients with BEN, ANC >1000/ μ L.
- Monitoring frequency and follow-up labs should be determined by your prescriber's discretion.

Source: <https://clozaril.com/wp-content/uploads/2022/12/HLS-Clozaril-PM-US.pdf>

Self-Advocacy

If a pharmacist or provider says clozapine is 'on hold' due to REMS, let them know:

- REMS was officially discontinued February 24, 2025.
- Certification is no longer required.
- The FDA no longer requires pharmacies or prescribers to log into the REMS system.

FDA Statement:

<https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-clozapine>

Watch for These Symptoms

Call your provider immediately if you experience:

- Fever, sore throat, or flu-like symptoms
- Severe constipation or stomach pain
- Confusion, seizures, or unusual drowsiness