CLOZAPINE REMS

The Single Shared System for Clozapine

No Blood, No Drug™

A Guide for Patients and Caregivers:

What You Need to Know about Clozapine and Neutropenia

What is clozapine?

Clozapine is a prescription medicine to treat people with schizophrenia who have not responded to other medicines. Clozapine may also reduce the risk of suicidal behavior.

What is the most serious risk information about clozapine treatment?

Clozapine can cause severe neutropenia, which can lead to serious infections and death. Neutropenia is a blood disorder that occurs when a certain type of white blood cells called neutrophils are not made or not enough of them are made. This makes it harder for your body to fight infections.

Before you can start clozapine and during treatment, you must have regular blood tests to measure the number of neutrophils you have in your blood. This test is called absolute neutrophil count (ANC). If the number of neutrophils, or ANC, is too low, you may have to stop clozapine. Your doctor will decide if or when it is safe to restart clozapine.

This is not the only serious risk associated with clozapine treatment. Talk to your doctor about the other serious risks.

What are the symptoms of neutropenia?

You might not have any symptoms at all. Getting your blood tested to measure the number of neutrophils is the only way to check for neutropenia. This helps your doctor know if you are more likely to get an infection.

If you have any of these symptoms, talk to your doctor right away

- Infection, including skin, throat, urinary tract, vaginal, pneumonia, or any other infection
- Fever or chills
- Sores or ulcers inside your mouth, gums, or on your skin
- Wounds that take a long time to heal
- Feel like you have the flu
- Pain or burning while urinating
- Unusual vaginal discharge or itching
- Abdominal pain
- Sores or pain in or around your rectal area
- Feel extremely weak or tired

What can I do to help reduce the risk of developing neutropenia?

Three important things you can do:

1. Have your blood tested as instructed by your doctor.
2. Tell your doctor about all the medicines you are taking (prescription and over-the-counter) and if you start a new medicine.
3. Tell your doctor right away if you get a fever or feel sick.

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

Because of the risk of developing severe neutropenia, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS) for clozapine. The purpose of the Clozapine REMS Program is to make sure that the benefits of clozapine treatment outweigh the risks.

What are the Clozapine REMS Program requirements for me?

To receive Clozapine:

1. **Review this Guide** with your doctor, pharmacist, or nurse.
2. Ask questions! **Make sure you understand** what you need to do to take part in the Clozapine REMS Program.
3. **Get your blood tested** as directed by your doctor. You must get your blood tested before you can receive clozapine from your pharmacy.
4. **Pick up your clozapine prescription** from a pharmacy that is part of the Clozapine REMS Program. Your doctor will help you find a pharmacy that participates in the Clozapine REMS Program.
5. **Tell your doctor** right away if you suffer any flu-like illness or fever while taking clozapine.

What are blood testing requirements for clozapine?

Get your Blood Tested	• Your doctor will give you an order to have blood tests done. • You will need to get your blood tested on the following schedule or as directed by your doctor: - Weekly blood tests for the first 6 months you are taking clozapine - Every 2 weeks for the next 6 months if your ANC stays normal - Monthly after the first year if your ANC stays normal
Monitoring Results	• If your ANC is too low, your doctor will schedule blood tests more frequently.
Stay on Clozapine	• The Clozapine REMS Program will keep track of your blood test results so your doctor and pharmacist know if it is safe to fill your clozapine prescription.
No Blood No Drug	• *Remember: You must get your blood tested before you can receive clozapine from your pharmacy!*

Where can I get more information about clozapine?

If you would like more information, talk to your doctor or visit www.clozapinerems.com.

Report any side effects directly to the Clozapine REMS Program at 844-267-8678.
You can also report negative side effects to the FDA at www.fda.gov/medwatch, or call 800-FDA-1088.