CLOZAPINE REMS

A Guide for Patients and Caregivers:

What You Need to Know about Clozapine and Neutropenia

Patients:
- Review this Guide with your doctor, pharmacist, or nurse.
- Ask questions!
- Make sure you understand what you need to do to receive Clozapine.

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 of clozapine treatment?

Clozapine can cause a blood condition (severe neutropenia), which can lead to serious infections and death. Neutropenia occurs when you have too few of a certain type of white blood cells called neutrophils. This makes it harder for your body to fight infections.

Why do I need to have blood tests?

Getting your blood tested is important because a low number of neutrophils may not cause any symptoms until you have an infection. Having a blood test helps your doctor know if you are more likely to get an infection.

You must have regular blood tests before you start taking clozapine and during your treatment. 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.

What are the symptoms of infection?

- 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

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

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, feel sick, or have any signs of infections.

What are the 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

Results	• If your ANC is too low, your doctor will schedule blood tests more frequently.
Stay on Clozapine	• The Clozapine REMS will keep track of your blood test results so your doctor and pharmacist know if it is safe to fill your clozapine prescription.

How do I receive my clozapine from the pharmacy?

Only certain pharmacies are allowed to provide you with clozapine. Your doctor will help you find a pharmacy.

Remember: You must get your blood tested before you can receive clozapine from your pharmacy!

What is the Clozapine <u>R</u>isk <u>E</u>valuation and <u>M</u>itigation <u>S</u>trategy (REMS)?

A REMS is a drug safety program that the U.S. Food and Drug Administration (FDA) can require for certain medicines with serious safety concerns. Drug companies and healthcare providers must take extra steps to make sure the benefits of using the drug are more than the risks.   Clozapine has a REMS because treatment with clozapine may cause a blood condition (severe neutropenia), which can lead to serious infections and death.

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 at **888-586-0758**.
You can also report negative side effects to the FDA at www.fda.gov/medwatch, or call **800-FDA-1088**.