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GenCAN
Gen-Clozapine ACCESS Network
Monitoring With Confidence

HEMATOLOGICAL MONITORING GUIDELINES*

Status	Action
GREEN STATUS WBC > $3.5x10^9$/L ANC ≥ $2.0x10^9$/L	Continue clozapine treatment. CBC and differential lab work once weekly, every 2 weeks or every 4 weeks. Pharmacy continues to dispense clozapine once weekly, every 2 weeks or every 4 weeks.
CLINICAL SAFETY ALERT: YELLOW STATUS **Low Values:** WBC $3.5x10^9$/L -$2.0x10^9$/L ANC $2.0x10^9$/L -$1.5x10^9$/L **Falling Values:** WBC Fall ≥ $3.0x10^9$/L Measured in the last 4 weeks reaching a value < $4.0x10^9$/L. ANC Fall > $1.5x\ 10^9$/L Measured in the last 4 weeks reaching a value < $2.5x10^9$/L. **Physical Symptoms:** Flu-like complaints or other symptoms which might suggest infection.	Continue clozapine treatment. CBC and differential lab work x 2/week. Evaluate for flu like complaints, fever, signs and symptoms of infection.
CLINICAL SAFETY ALERT: RED STATUS WBC < $2.0x10^9$/L ANC < $1.5x10^9$/L *Note: WBC < $1.0\ x10^9$/L ANC < $0.5\ x\ 10^9$/L	Repeat CBC and differential within 24 hrs to confirm results. Pharmacy contacts physician for dispensing direction. Results confirmed = STOP clozapine treatment CBC and differential continue weekly x 4 weeks. Evaluate for flu like complaints, fever, signs and symptoms of infection. **CLOZAPINE TX MUST NOT BE RESUMED: PATIENT NON-RECHALLENGEABLE** Protective isolation is recommended, if evidence of infection develops, appropriate cultures and antibiotic regime should be performed.

* Please consult product monograph for complete hematological monitoring information.

GEN-CLOZAPINE (clozapine) is indicated in the management of symptoms of treatment-resistant schizophrenia. In controlled clinical trials, clozapine was found to improve both positive and negative symptoms. Due to the significant risk of agranulocytosis and seizure associated with its use, clozapine should be limited to treatment-resistant schizophrenic patients who are non-responsive to, or intolerant of, conventional antipsychotic drugs. Clozapine can be used only if regular hematological examinations can be guaranteed, as specified under WARNINGS and DOSAGE AND ADMINISTRATION. Physicians should not prescribe Gen-Clozapine until the non-rechallengeable status and the hematological status of the patient has been verified. The extended treatment of patients failing to show an acceptable level of clinical response to GEN-CLOZAPINE (clozapine) should ordinarily be avoided. In addition, the need for continuing treatment in patients exhibiting beneficial clinical responses should be reassessed periodically.

Elderly patients with dementia treated with atypical antipsychotic drugs are at an increased risk of death compared to placebo. Gen-Clozapine is not indicated in elderly patients with dementia. The use of clozapine is associated with an increased risk of myocarditis (especially during, but not limited to the first month of therapy), pericarditis, pericardial effusion, cardiomyopathy, heart failure, myocardial infarction and mitral insufficiency. The occurrence of signs and symptoms of these disorders necessitates an urgent diagnostic evaluation by a cardiologist. If myocarditis is suspected, clozapine should be promptly discontinued. Patients with clozapine-induced myocarditis should not be re-exposed to clozapine. Clozapine is contraindicated in patients with severe cardiac disease.

Gen-Clozapine is restricted to patients who have a normal white blood cell (wbc) count and differential count prior to starting clozapine therapy. Subsequently, a wbc count and differential count must be carried out at least weekly for the first 26 weeks of treatment with clozapine. Thereafter, if acceptable wbc counts and absolute neutrophil counts (anc s) (wbc ≥ 3500/mm³ and anc ≥ 2000/mm³) have been maintained during the first 26 weeks of continuous therapy, the wbc count and differential count can be performed at least at two week intervals for the next 26 weeks. Thereafter, if acceptable wbc counts and ancs (wbc ≥ 3500/mm³ and anc ≥ 2000/mm³) have been maintained during the second 26 weeks of continuous therapy, the wbc count and differential count can be performed at least every four weeks throughout treatment. Please consult product monograph for complete warning, precautions, adverse events and patient selection criteria.

GEN-CLOZAPINE
25mg, 50mg, 100mg and 200mg tablets

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