

The Food and Drug Administration (FDA) has just released a Drug Safety Communication regarding changes in the requirements for monitoring, prescribing, dispensing and receiving clozapine. There are two major changes: 1) FDA now indicates that neutropenia will be monitored by absolute neutrophil count (ANC) only, rather than in conjunction with the white blood cell (WBC) count 2) FDA has approved a new shared risk evaluation and mitigation strategy (REMS) called the Clozapine REMS Program. The Clozapine REMS Program replaces the six registries maintained by individual clozapine manufacturers with a single centralized program. In order to prescribe and dispense clozapine, prescribers and pharmacies will be required to be certified in the Clozapine REMS Program according to a specific transition schedule starting *October 12, 2015*.

Please see link for further information

http://www.fda.gov/Drugs/DrugSafety/ucm461853.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery