

# AZUR PHARMA

## WBC Counts Reduced to Monthly for FazaClo® (clozapine, USP) Orally Disintegrating Tablets Patients After One Year

May, 2005

Dear Doctor:

Azur Pharma is pleased to announce a new Food and Drug Administration (FDA)-approved reduction in the frequency of required white blood cell (WBC) and absolute neutrophil counts (ANC) testing for patients receiving FazaClo® who have experienced 12 months of acceptable test results.

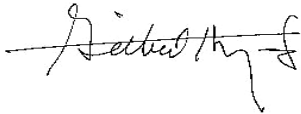
Officials of the US FDA and its advisors have reviewed information on clozapine and the existing WBC testing requirements. Since the regulators' review indicated that roughly 85% of agranulocytosis reports for patients receiving clozapine occur within the first year, the residual risk to patients after one year of continuous clozapine treatment appears to be comparable to other antipsychotic medicines. For patients who experience no unusual hematological events, the newly approved schedule of testing is as follows: weekly WBC and differential counts for the first six months; for the next six months, if there have been no hematological problems, the schedule of required blood tests goes down to once every two weeks. After one year of acceptable blood testing results -- both total white blood cell counts and absolute neutrophil counts (ANC) -- WBC and differential testing may be reduced to every four weeks.

Should you have any questions concerning required blood testing, please feel free to contact me or your local Azur Pharma Sales Specialist. Or, for further information, you might want to visit the website: [www.fazaclo.com](http://www.fazaclo.com).

New, full prescribing information for FazaClo is enclosed, complete with boxed warnings regarding agranulocytosis, seizures, myocarditis, and cardio-respiratory events. More complete information may be found on the website [www.fazaclo.com](http://www.fazaclo.com). If you'd like to speak with us directly, please call at your convenience – the number is 877-FAZACLO (877-329-2256).

Thanks. We'll be in touch again.

Sincerely,



Gilbert Honigfeld, Ph.D.  
Vice President, Scientific Affairs

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