PATIENT DIARY SUMMARY (PD)

DATA SECTION	COMPLETION INSTRUCTIONS
PURPOSE	To capture information related to missed doses of the study medication and number of alcoholic drinks during each interval between protocol visits.
PERSON(S) RESPONSIBLE	Study Coordinator/study physician
SOURCE(S) OF INFORMATION	Patient completed diary and Medi-dose cup counts
WHEN TO ADMINISTER FORM	Treatment Weeks 2, 4, 8, 12, 20 and 24
GENERAL INFORMATION	The Patient Diary Summary (PD) form is a running log sheet that tracks the number of dose cups dispensed and returned at each protocol visit and patient self-report information from the patient diaries. The coordinator must instruct the patients to bring the completed diary and all unused dose cups to each protocol visit. The log sheet is initiated at the baseline visit and then updated at the time of each protocol visit through the end of the treatment period. At each protocol visit, the coordinator must review the patient diary and then calculate the number of missed doses and the average number of drinks per day since the last protocol visit. Dispensing Guidelines: - dispense 9 extra dose cups at the baseline and all other protocol visits (to accommodate the ± 3 day window around later timepoints) - it is acceptable to re-dispense (to the same patient) unused dose cups that are returned Record the Patient ID number in the top left hand corner of the page.
	SPECIFIC INSTRUCTIONS:
PATIENT ID	First Dose: record the date (day/month/year) and time (hour: minute) the first dose of the study medication is taken.
BASELINE	Number of Cups Dispensed: record the number of cups (1 cup contains 5 capsules) dispensed at the baseline visit (at the start of treatment) Visit Date: Record the date (day/month/year) of the treatment visit. Number of Cups Returned: Record the number of unused dose cups returned by the patient.
TREATMENT WEEKS	Number of Doses Missed During Interval: Record the number of doses missed since the previous treatment visit, according to the information recorded on the patient diary. If for some reason the patient indicates that they missed part of a dose, count the partial dose as a missed dose. Number of Cups Dispensed: record the number of dose cups dispensed for the upcoming treatment interval. Average Number of Drinks Per day During Interval: using information recorded on the patient diary, calculate the average number of drinks per day since the previous protocol visit. Last Dose Prior to Visit Date: record the date (day/month/year) of the last dose taken prior to the visit

DATA SECTION	COMPLETION INSTRUCTIONS
	Time: record the time (hour:minute) of the last dose taken prior the visit Did Not Review Diary: check if the patient diary was not reviewed during the visit (e.g. patient forgot diary, coordinator did not review diary).