

Site Number: _____ Screening ID: _____ - ____ First 3 Letters of First Name: _____

This form is completed to record the details of any **serious adverse events** that occur during this study. This form should be completed with as much information as is known and faxed to the TrialNet Coordinating Center at **(301) 468-1676** within **24 hours** of clinic notification that an event had occurred. **Attach additional pages, if needed.**

A. MEDWATCH Report Information

1. Report Date: ____/____/____
MM DD YYYY

2. Report By: _____

3. Phone #: _____

4. Reason for Report (*check all that apply*):

1 Death 4 Life-threatening 6 Hospitalization*

2 Overdose 5 Congenital anomaly/birth defect

* Initial or prolonged 3 Treatment to prevent a serious event or outcome 7 Disability/Incapacitay

9 Other: a. _____

5. Adverse Event ID #: _____

B. Patient Information

1. Age: ____ 2. Gender: M F 3. Weight: ____ kg OR ____ Lb

4. Serious Adverse Event Being Reported: _____

5. Onset Date: ____/____/____ 6. Current Status: 1 AE Ongoing 2 AE cleared on: a. ____/____/____
MM DD YYYY

7. Describe the Adverse Event, including treatment of the event (e.g., comment on the patient's condition just prior to the adverse event, the onset and development of the event, and **-If known at time of this report-**the duration and outcome of the adverse event.):

8. Pertinent Medical History (including Pre-Existing Medical Conditions):

9. Concomitant Medications Taken at the Time of Onset of the Adverse Event:

10. Pertinent Laboratory Test Results (both Normal and Abnormal):

C. Study Medication Information

1. Randomization Date: ____/____/____ 2. Daily Dosage at Time of Adverse Event: ____ mg
MM DD YYYY

3. Frequency of Dosing at Time of Event: 1 BID 2 TID 9 Other 4. Date This Dose Started: ____/____/____
MM DD YYYY

5. Dose Following Event: 1 Unchanged 2 Reduced 3 Interrupted 4 Discontinued 9 NA

6. If Dose Reduced, Interrupted or Discontinued, Did Patient Improve? 1 Yes 2 No (*not yet*) 9 NA

7. If Dose Reduced, Interrupted or Discontinued, Do You Plan to Re-start Patient and/or Return to Higher Dose? 1 Yes (*or already have*) 2 No 3 Undecided

8. If Patient Re-started on Study Medication, or Returned to Higher Dose, Did Adverse Event Reappear? 1 Yes 2 No 9 NA



**MMF-DZB Study
MEDWATCH FORM**

Form MMFSA

July 06, 2004
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