Study ID: ________________
Visit Date: _______________
Mo - Day – Year
Visit 3

Vital Signs

Please mark if evaluation was not done ☐

Any significant findings after the start of the study drug should be recorded on the Adverse Events page.

Please circle the correct measurement, when applicable.

Weight ______________kg or lbs

Sitting Pulse _______________bpm

Sitting Blood Pressure _______/_______ systolic/diastolic MmHg

Respirations ______________/minute

Temperature ______________degrees Centigrade or Fahrenheit

Study ID: ________________
Visit Date: ________________
Mo - Day – Year
Visit 3

Collect Symptom Diary

|__|__|__|__|__|__|__|__|
Month Day Year

0____No

1____Yes

Dispense Symptom Diary

|__|__|__|__|__|__|__|__|
Month Day Year

0____No

1____Yes

Dispense Study Drug

|__|__|__|__|__|__|__|__|
Month Day Year

0____No

1____Yes

Dispense Medication Diary

|__|__|__|__|__|__|__|__|
Month Day Year

0_____No

1____Yes

Study Drug Dispensed as

0_______Dose Cards (Non Child Resistant)

1_______Vials (Child Resistant)

Study ID: ________________
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Visit 3

Concomitant Medication/Significant Non-Drug Therapies prior to and after start of study drug.

- Please list all medication and significant non-drug therapies.
- If there are no changes from previous visit, enter **NO CHANGES** (on line 1 below).

Period covered by this form: Start Date (visit 1) |___|___|___|___|___|___|___|___| Month Day Year End Date (visit 3) |___|___|___|___|___|___|___|___| Month Day Year

Medication/Non-Drug Therapy (use trade name if possible & list dose)	Reason (Including Prophylaxis)
1.________________	________________
2.________________	________________
3.________________	________________
4.________________	________________
5.________________	________________
6.________________	________________
7.________________	________________
8.________________	________________
9.________________	________________
10.________________	________________
11.________________	________________
12.________________	________________
13.________________	________________
14.________________	________________
15.________________	________________
16.________________	________________
17.________________	________________

Is an additional Concomitant Medications/Significant Non-Drug Therapies page used? **0___No** **1___Yes**

Please ensure that the data on this page are consistent with the data on the Relevant Medical History/Current Medical Conditions page of Visit 1.

Study ID: ________________
Visit Date: _______________
Mo - Day – Year
Visit 3

.

Weekly Phone Call for Weeks 1-3 After Visit 3

Phone Call Date __ __/ __ __/ __ __ __ __

1. How are you feeling?
____
____

2. In the past week, have you had adequate relief of your stomach symptoms? No = 0 Yes = 1

3. Have you missed any doses of the study medication? No = 0 Yes = 1
If yes, how many doses and reason.
Number of missed doses______
Reason for missed doses____
____

4. Have you started any new medicines (either prescribed or over the counter) since your last visit? No = 0 Yes = 1
If yes, what medicines?____
____

5. Since starting the study have you noticed a change in your mood? No = 0 Yes = 1
If yes, obtain description from the participant
____
____
____

If the participant describes a depressed mood, obtain answers to the following questions:

a. I still enjoy the things I used to enjoy:
1.___Definitely as much
2.___Not quite as much
3.___Only a little
4.___Hardly at all

b. I can laugh and see the funny side of things:
1.___As much as I always could
2.___Not quite as much now
3.___Definitely not as much now
4.___Not at all

c. I feel as if I am slowed down:
1.___Nearly all the time
2.___Very often
3.___Sometimes
4.___Not at all

Study ID: ________________
Visit Date: _______________
Mo - Day – Year
Visit 3

(Phone Call Date __ __/ __ __/ __ __ __ __)

d. I have lost interest in my appearance:
1.___Definitely
2.___I don't take as much care as I should
3.___I may not take as much care
4.___I take as much care as ever

e. I feel cheerful:
1.___Not at all
2.___Not often
3.___Sometimes
4.___Most of the time

f. I look forward with enjoyment to things:
1.___As much as I ever did
2.___Rather less than I used to
3.___Definitely less than I used to
4.___Hardly at all

g. I can enjoy a good book or radio or TV program:
1.___Often
2.___ Sometimes
3.___Not often
4.___Very seldom

Question 5 Total;_______________

If the participant's score for the questions is > or = to 11, the participant is to be seen for an unanticipated study visit. The Principal Investigator at each site will encourage the participant to seek follow up care.

6. Have you seen your health care provider since the last call? No = 0 Yes = 1

Date of Doctor visit **Date __ __/ __ __/ __ __ __ __**

If yes, why?
____
____
____
____

7. Thank you for answering my questions. Please contact _____(name of PI) *and/or* _____(name of coordinator) **prior to stopping the study medication**. If you feel you can not wait until business hours, please go to your nearest ER and contact us during business hours.

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Visit 3

Participant is to complete the following survey forms:

CGI ☐ Complete ☐ Incomplete Reason: ______________________________

SF – 36 ☐ Complete ☐ Incomplete Reason: ______________________________

NEPEAN ☐ Complete ☐ Incomplete Reason: ______________________________

GSRS ☐ Complete ☐ Incomplete Reason: ______________________________

Changes:

Were any changes made on any of the above questionnaires?

☐ NO ☐ YES (If yes, see below)

If yes, study coordinator initial and date HERE that the changes were made by the study participant at the time of completion of questionnaires. _________________________ |__|__|__|__|__|__|__|__|

Study coordinator initial Month Day Year