

**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 lb

**Sitting Pulse** \_\_\_\_\_ bpm

**Sitting Blood Pressure** \_\_\_\_\_ / \_\_\_\_\_  
systolic/diastolic  
MmHg

**Respirations** \_\_\_\_\_ /minute

**Temperature** \_\_\_\_\_ degrees Centigrade or Fahrenheit

**Full Blood Count**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Serum Chemistry**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Blood Levels for study drug**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Dispense Study Drug**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Collect Medication Diary**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Dispense Medication Diary**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Compliance Count**

\_\_\_\_\_ **Number of Tablets or doses  
returned**  
(please circle tablets or doses)

\_\_\_\_\_ **Number of Tablets or  
doses expected to be returned**  
(please circle tablets or doses)

**Collect Symptom Diary**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

**Dispense Symptom Diary**

|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year

0\_\_\_ No

1\_\_\_ Yes

PLEASE CHECK THAT ALL QUESTIONS HAVE BEEN ANSWERED.

THANK YOU FOR YOUR CO-OPERATION.

**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 3)**      **End Date (visit 4)**  
|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|      |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|      |\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year      Month Day Year      Month Day Year

**Medication/Non-Drug Therapy**  
(use trade name if possible)

**Reason**  
(Including Prophylaxis)

1.	_____	_____
2.	_____	_____
3.	_____	_____
4.	_____	_____
5.	_____	_____
6.	_____	_____
7.	_____	_____
8.	_____	_____
9.	_____	_____
10.	_____	_____
11.	_____	_____
12.	_____	_____
13.	_____	_____
14.	_____	_____

**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.

**Weekly Phone call for Weeks 1-3 after Visit 4**

**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

(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?

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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.

Participant is to complete the following survey forms:

CGI	<input type="checkbox"/> Complete	<input type="checkbox"/> Incomplete Reason: _____
SF – 36	<input type="checkbox"/> Complete	<input type="checkbox"/> Incomplete Reason: _____
NEPEAN	<input type="checkbox"/> Complete	<input type="checkbox"/> Incomplete Reason: _____
GSRS	<input type="checkbox"/> Complete	<input type="checkbox"/> Incomplete Reason: _____

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### **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