

**Visit 10**  
**Monthly Phone Call**

1. How are you feeling?

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

3. Have you started any new medicines (either prescribed or over the counter) since your last visit? \_\_\_\_\_ No = 0 Yes = 1

If no, go on to next question.

**If yes**, what medicines? (also list medications on page 3) \_\_\_\_\_

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4. Since starting the study have you noticed a change in your mood? \_\_\_\_\_ No = 0 Yes = 1

If no, go on to 4.a.

**If yes**, obtain description from the participant

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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

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

Total: \_\_\_\_\_

NOTE: Use SOP for Scoring the HADS questionnaire to score Question 4 (a-g)

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.

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

**IF Yes,** date of Doctor visit    **Date** \_\_\_ \_\_\_ / \_\_\_ \_\_\_ / \_\_\_ \_\_\_

**If yes,** why?

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**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 9)                      End Date (visit 10)  
|\_|\_|\_|\_|\_|\_|\_|\_|                      |\_|\_|\_|\_|\_|\_|\_|\_|                      |\_|\_|\_|\_|\_|\_|\_|\_|  
Month Day Year                      Month Day Year                      Month Day Year

<b>Medication/Non-Drug Therapy</b> (use trade name if possible)	<b>Reason</b> (Including Prophylaxis)
1. _____	_____
2. _____	_____
3. _____	_____
4. _____	_____
5. _____	_____
6. _____	_____
7. _____	_____
8. _____	_____
9. _____	_____
10. _____	_____
11. _____	_____
12. _____	_____
13. _____	_____
14. _____	_____
15. _____	_____
16. _____	_____

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 Medication History/Current Medical Conditions page of Visit 1.